EFFECTIVENESS OF APPLICATION OF FLAVORED ICE CUBES ON ORAL MUCOSITIS AMONG PATIENTS WITH CANCER RECEIVING CHEMOTHERAPY

A DISSERTATION SUBMITTED TO THE TAMILNADU DR.M.G.R MEDICAL UNIVERSITY, CHENNAI, IN PARTIAL FULFILMENT OF THE REQUIREMENT FOR THE DEGREE OF MASTER OF SCIENCE IN NURSING

APRIL 2014

CERTIFICATE

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"Those who are bewildered by the modes, not knower of the whole, let not the knower of the whole disturb in their mental stand point"

- Bhagawat Gita

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ABSTRACT

AIM: The study aimed to assess the effectiveness of flavored ice cubes on oral mucositis in patients with cancer receiving chemotherapy. BACKGROUND: This study evaluates the effect of application of flavored ice cubes in patients, on chemotherapy induced oral mucositis in combined chemotherapy regimens METHOD: The study consisted of total of 60 samples, 30 in experimental group and 30 in control group. Simple random sampling technique - lottery method was used to select samples. DESIGN: The design adopted for the study was pre-test post test true experimental control group design. The experimental group was given flavored ice cubes to place in their mouth for 5 minutes before the chemo drug infusion, 30 minutes during the infusion and 5 minutes after the infusion of the chemodrug. The control group received no intervention. Both the groups were treated with the following chemo drug combination (i) cisplatin + 5fu (ii) cisplatin + etoposide (iii) cisplatin + paclitaxel (iv) cisplatin + irinotecan (v) cisplatin + gemcitabine. The Oral Mucositis Assessment Scale was used for evaluation. RESULT: The results revealed that 70% of the samples in experimental group on pre test samples had mild ulceration and 56% had not severe erythema. After application of ice cubes, on 3rd day observation 50% had no ulceration and 70% had no erythema and on 21st day observation 73.33% had no ulceration and 60% had no erythema. In control group, on pretest 3.3% had mild ulceration, 60% had not severe erythema. On 3rd day observation 90% had mild ulceration, 96.6% had not severe erythema. On 21st day observation 70% had mild ulceration, 93.33% had not severe erythema.

In the pretest, majority of the samples in experimental group and control group had mild ulceration and not severe erythema. In the post test there was improvement in the reduction of oral mucositis in the experimental group whereas in the control group majority of the samples continued to have mild oral mucositis. There was an association between the oral mucositis and tobacco chewing, oral mucositis and the chemodrug usage. The combination of cisplatin+5fu and cisplatin+etoposide showed significant association in developing oral mucositis among the other chemodrug combinations enlisted.

CONCLUSION: Oral cryotherapy makes an important contribution to the protection of oral health. Because of its easy of application, tolerability, and lack of side effects, has become an important remedy for reducing the incidence and severity of oral mucositis.

CHAPTER - I

INTRODUCTION

"Growth for the sake of growth is the ideology of the cancer cells"

- Author unknown

Human body is the most beautiful and generous creation of God. It has got the ability to adapt to the various situations provided, and vigorous climate conditions but sometimes, some conditions or factors, especially the ones resulting from the industrialization can harm it drastically and force it to death.

A healthy cell does not turn into a cancer cell overnight. Richard, David and Faragher, described that the first rule of cancers is that they follow no rules. Cancer cells exhibit dysplasia, hyperplasia, metaplasia, and pleomorphism.

Cancer is a group of more than 200 diseases characterised by uncontrolled and unregulated growth of cells. It is a major health problem that occurs in people of all ethnicities. Although cancer is often considered as disease of ageing, with the majority of cases diagnosed (76%) in over the age of 55 years it occurs in people of all ages. Globally cancers account for 5.1% of total disease burden and 12.5% of all deaths. In India they account for 3.3% of disease burden and 9.9% of all deaths. With the increasing prevalence of tobacco and alcohol consumption in the country, it is estimated that 10 lakh new cases will be diagnosed in 2016, up from about 8 lakhs in 2001. Nearly 6,70,000 people are expected to die in the year 2016 due to cancer, in India. (Chintamani and Lewis, 2011),

According to International Agency for Research on cancer,*American Cancer soceity, (2011),* it was estimated that there were about 12.7 million new cancer cases and 7.6 million

cancer deaths in 2008 worldwide. Overall incidence rates (per 100,000) for 1998-2002 among the 45 selected cancer registries worldwide vary by nearly 6-fold in men, from 86.3 in Algeria (Setif) to 453.3 in U.S. blacks, and by nearly 4-fold in women, from 80.3 in Algeria (Setif) to 302.3 in U.S. non-Hispanic whites By 2030, the global burden is expected to grow to 21.4 million new cancer cases and 13.2 million cancer deaths simply due to the growth and aging of the population.

Maddireddy Umameshwar Rao Naidu, Gogula Venkat Ramana, Pingali Usha Rani, Iyyapu Krishna Mohan, Avula Suman, and Priyadarshni Roy, (2004)., described that, Chemotherapy and radiation therapy are the most widely used interventions for the treatment of cancer. Although these treatments are employed to improve the patient's quality of life, they are associated with several side effects. Severe adverse reactions due to these therapies result in patient morbidity and mortality. The major objective of cancer therapy is to treat the client with appropriate therapy for sufficient duration. So that the cure results with minimal functional and structural impairment. The goal of chemotherapy is to destroy as many tumor cells as possible with minimal effect on healthy cells. It can be used for cure, control, and palliation. Chemotherapy induced side effects are the result of destruction of the normal cells, especially those that are rapidly proliferating such as those in the bone marrow, the lining of the GI system, and the integumentary system. There may be acute and delayed effects.

The development of oral mucositis is a delayed effect of chemotherapy. Mucositis is the common side effect for cancer patients receiving chemotherapy and radiation therapy, and can occur anywhere along the digestive tract from mouth to the anus (Newton, Hicky and Mars 2009).

Oral complications are frequent and troublesome symptoms for those undergoing chemotherapy for cancer. Several anti neoplastic agents are proved to have stomatotoxic potential, among them 5-FU, is found to have higher effect. (Djuric, Hillier-kolarov, Belic, Jankovic, 2006),

According to mayoclinic.org, (2011), annually, there are approximately 4, 00,000 cases of treatment – induced damage to the oral cavity. There are many types of chemotherapy that are known to cause oral mucositis. Some of these therapies are 5-fluorouracil, methotrexate, doxorubicin, etoposide, melphalan, cytosine arabinoside, cyclophosphamide, and cisplatin.

Witt, (2007) Oral mucositis is the debilitating symptom which can have a profound effect on the quality of life of a person diagnosed with cancer) Witt, (2007). Oral mucositis lead to pain which can become so severe that the patient is unable to eat or drink and can undermine the willingness to continue with chemotherapy.Douherty & Bailey, (2008). Oral mucositis can also lead to chemotherapy dose reductions, cessation of chemotherapy, hospitalisations, reliance on parenteral nutrition & even death Sonis (2007).

Rajesh lalla, Stephen sonis, Douglas Peterson, (2008), stated that, A wide variety of scales have been used to record the extent and severity of oral mucositis in clinical practice and research. The World Health Organization scale is a simple, easy to use scale that is suitable for daily use in clinical practice. This scale combines both subjective and objective measures of oral mucositis. The National Cancer Institute Common Terminology Criteria for Adverse Events version 3.0 includes separate subjective and objective scales for mucositis. The Oral Mucositis Assessment Scale (OMAS) is an objective scale, suitable for research purposes, that measures erythema and ulceration at nine different sites in the oral cavity. This scale has been validated in a multi-center trial with high inter-observer reproducibility and strong correlation of objective

mucositis scores with patient symptoms . The Eastern Cooperative Oncology Group common toxicity criteria are also used in oncology trials to document severity of oral mucositis . (Rajesh lalla, Stephen sonis, Douglas Peterson, 2008)

According to Cancer Care, (2011), "Cold therapy" is a technique that nurses devised for people receiving the chemotherapy 5-FU. Starting five minutes before getting the drug and continuing for about half an hour, patients suck on ice chips. This closes the blood vessels in the mouth so that they are less affected by the drug as it goes through the bloodstream. (The damaging effects of 5-FU tend to drop off after half an hour). Studies show that people who use the ice chips have about half the amount of mouth sores and pain as people who do not use the ice chips. The technique has also been used with other types of chemotherapy.

Nursing assessment and patient education will help alleviate the common and distressing symptom of oral mucositis. More research is needed to examine effective interventions, but healthcare professionals can rely oral care protocols to maintain patients' functional status and quality of life. This evidence based practice will enhance quality and standards of nursing care given to the patient in the management of oral mucositis, and improves to the treatment compliance.

NEED AND SIGNIFICANCE OF THE STUDY

"**Our food should be our medicine and our medicine should be our food."**

~ Hippocrates

According to www.cancer.org, (2011), almost half of the people who are treated with chemotherapy and nearly everyone receiving head and neck radiotherapy or a Hematopoietic Stem Cell Transplant (HSCT) will get oral mucositis (OM).As well as the type of cancer being treated, the likelihood of developing oral mucositis varies depending on the situation, lifestyle

and medical history of the person. Those at particular risk are like young people and the elderly, those with previous oral health problems or oral mucositis, people who have poor oral hygiene during treatment, smokers, people who drink alcohol, diabetic patients, those receiving certain types of chemotherapy

According to virtualmedicalcentre.com, (2010)., Oral mucositis is the initiation, inflammation and or ulceration of the mucosa. It is the commonest complications to almost all patients receiving radiation to head and neck and in significant patients receiving 5-FU. Oral mucositis is the complex problem involving not only the epithelial lining but also the other mucosal components, including the endothelial, extracellular matrix and connective tissue.

There are two types of mucositis, namely, direct mucositis and indirect mucositis**.** Direct mucositis is Maturity and cellular growth of epithelial cells, causing changes to the normal turn over and cell death. Indirect mucositis caused by the indirect invasion of gram-negative bacteria and fungal species. This usually happens when indirect stomatotoxicity appears. (Maddireddy Umameshwar Rao Naidu, Gogula Venkat Ramana, Pingali Usha Rani, Iyyapu Krishna Mohan, Avula Suman, and Priyadarshni Roy, 2004)

According to www.nvydiamedical.com, (2013), patients below 20 years are more likely to develop OM, as are those over age 50 years. Patients with poor renal function, diabetes or HIV are more vulnerable, as are those with poor oral hygiene or existing oral problems. Patients who use tobacco or alcohol also are more vulnerable People being treated with the chemotherapeutic medications fluorouracil and cisplatin are most likely to develop OM (90% of cases).

According to Poon & Sze-wan, (2012), oral mucositis is the common adverse side effect caused by cancer treatment and can lead to mucosa toxicity. Patients with oral mucositis may

experience extreme pain and may not be able to eat, drink and talk. As a result their quality of life is impaired. Nearly, 30 – 85 % of patients undergoing chemotherapy would develop oral mucositis.

Castelinoflavia (2011)., done a study which focused on the prevention of mucositis among cancer patients receiving 5-FU using plain vs flavored ice cubes to care their pain and improve their quality of life with fewer complications. The results showed that the flavored ice cubes were effective in preventing the oral mucositis and the patients were in favor of the flavored ice cubes.

According to the Study conducted by , Lilleby ,Garcia, gooley, (2006)., in Fred Hutchinson Cancer Research Centre, 40 patients receiving high-dose melphalan followed by Peripheral Blood Stem Cell Transplantation utilized cryotherapy or normal saline rinses before, during and after chemotherapy. Compared to the normal saline group, the patients who used cryotherapy had lower average National Cancer Institute mucositis scores, a lower incidence of grades 3–4 mucositis, less use of narcotics and Total Parental Nutrition, and lower average patient-reported pain scores. Each of these differences was statistically significant. In addition, patient-reported activities of swallowing, eating, drinking, talking, sleeping and taste were less impaired in the cryotherapy group, and each of these differences was statistically significantly or suggestively different. These data support the hypothesis that cryotherapy reduces the severity and incidence of mucositis, with resulting clinical benefit in patients undergoing high-dose melphalan.

Evans, (2008), described that, The mucositis may affect the patient's gum and dental condition, speech and self esteem are reduced further compromising patient's response to treatment and or

palliative care. scully, Epstein, sonis (2003)., described that mucositis also affects the survival because of the risk of infection and has a significant impact on quality of life and cost of care. Chemotherapy induced mucositis is generally limited to non-keratinised mucosa and most commonly involves the soft palate, ventrum of tongue /floor of the mouth, and buccal mucosa.

"Oral cryotherapy, the therapeutic administration of cold is a prophylactic measures for oral inflammation." The goal of chemotherapy is to destroy as many tumor cells as possible with minimal effect on healthy cells. But still, side effects like oral mucositis are unavoidable. Inorder to promote the patients well being and to prevent the malnourishment due to lack of tolerance, cryotherapy is preferred. Considering the study support of oral cryotherapy for oral mucositis the researcher believed that this could bring positive effects on the patient's health status. Preventing mucosal injury will pave better way for patients to cope up with chemotherapy and improve quality of life, hence researcher underwent this study.

STATEMENT OF THE PROBLEM:

An experimental study to evaluate the effectiveness of application of flavored ice cubes on oral mucositis among patients with cancer receiving chemotherapy in Devaki Cancer and Research Institute, Madurai.

OBJECTIVES OF THE STUDY:

- To determine the level of oral mucositis among patients with cancer receiving chemotherapy in experimental group before and after using flavored ice cubes.
- To determine the pre and post test level of oral mucositis among patients with cancer receiving chemotherapy in control group.
- To check the effectiveness of flavored ice cubes on oral mucositis among patients with cancer receiving chemotherapy.

- To find out the association between the pre test level of oral mucositis among patients receiving chemotherpay and selected demographic variable.(age, sex, education, occupation, habits of kutka, pan masala, betel nut, tobacco chewing, smoking, type of ancer and chemo drugs used).

HYPOTHESES:

- The mean post-test level of oral mucositis score among patients with cancer on chemotherapy who received the flavored ice cube will be significantly lower than their mean pre-test level of oral mucositis score in experimental group.
- The mean post test level of oral mucositis score in experimental group of patients with cancer on chemotherapy after receiving the flavored ice cubes will be significantly lesser than the mean post test score of patients with cancer on chemotherapy in control group.
- There will be significant association between the pre test level of oral mucositis score with demographic variables(age, sex, education, occupation, habits of smoking, tobacco chewing, kutka, panmasala chewing, type of cancer and type of chemo drugs)

DEFINITION OF TERMS:

EFFECTIVENESS: It refers to the change produced by an action or a cause.

In this study, it refers to the outcome of flavored ice cube in reducing the oral mucositis among cancer patients receiving chemotherapy, which was measured by the score obtained by subjects in oral mucositis assessment scale (OMAS)

FLAVORED ICE CUBES: It refers to 'Trapezium prism' shaped cubes of ice prepared in combination with milk and vanilla essence. The Ice cubes were freezed in the degree of -4degree celcius to -5 degree celcius for duration of minimum 8 hours to maximum 12 hours.

The trapezium prism shaped ice cube has an top and base rectangular shape. It has 1 height (H), 2 length (L1, L2), and two breadth (B1 , B2).

The size of the ice cube in centimeter is, 3.9(L1) * 3.6(L2) * 1.4(H) * 1.5 (B1)* 0.9(B2).

ORAL MUCOSITIS: It refers to the inflammation of the oral mucous membrane as evidenced by the soreness, erythema, ulceration as determined by the oral mucositis assessment scale

PATIENTS ON CHEMOTHERAPY: It refers to both male and female patients with cancer, receiving chemotherapeutic agents Intravenously like Cisplatin +5FU, Cisplatin + Etoposide, Cisplatin + Paclitaxel, Cisplatin + Irinotecan, Cisplatin + Gemcitabine in Devaki Cancer and Research Institute, Madurai.

ASSUMPTIONS:

- Mucositis may compromise the nutritional status and quality of life of the cancer patients receiving chemotherapy.
- The cooling of the oral mucosa using ice chips will reduce the blood flow to the oral mucosa, thus reducing the availability of chemotherapeutic agents to the oral mucosa.
- Severity of oral mucositis may vary from individual to individual.

DELIMITATIONS:

- The study is delimited to patients with cancer receiving chemotherapy in selected hospitals at Madurai.
- Application of ice cube in oral cavity were given only for the subjects who received chemo drug infusion for the period of 3 days.

PROJECTED OUTCOME:

The study will reveal the level of oral mucositis while using flavored ice cubes, the results of the study will show there is or significant reduction in oral mucositis among cancer

patients using flavored ice cubes. The findings of the study will help the health professionals to give flavored ice cubes before, during and after the chemotherapy for patients with cancer.

CONCEPTUAL FRAMEWORK

The study is based upon the **J.W.KENNEY'S OPEN SYSTEM MODEL**

The main concepts of system model are input, throughput, and output

INPUT

Input refers to the matter, energy and the information that enters into the system through its boundary.

In this study flavored ice cubes are applied in the oral mucosa, 5minutes before chemo drug infusion for 30 minutes and for 5minutes after chemo drug infusion.

THROUGHPUT

Throughput refers to the process where the system transforms energy, matter and information.

In this study it refers to the effect of vasoconstriction which decreases the exposure of the chemo drug to the oral cavity mucous membranes.

OUTPUT

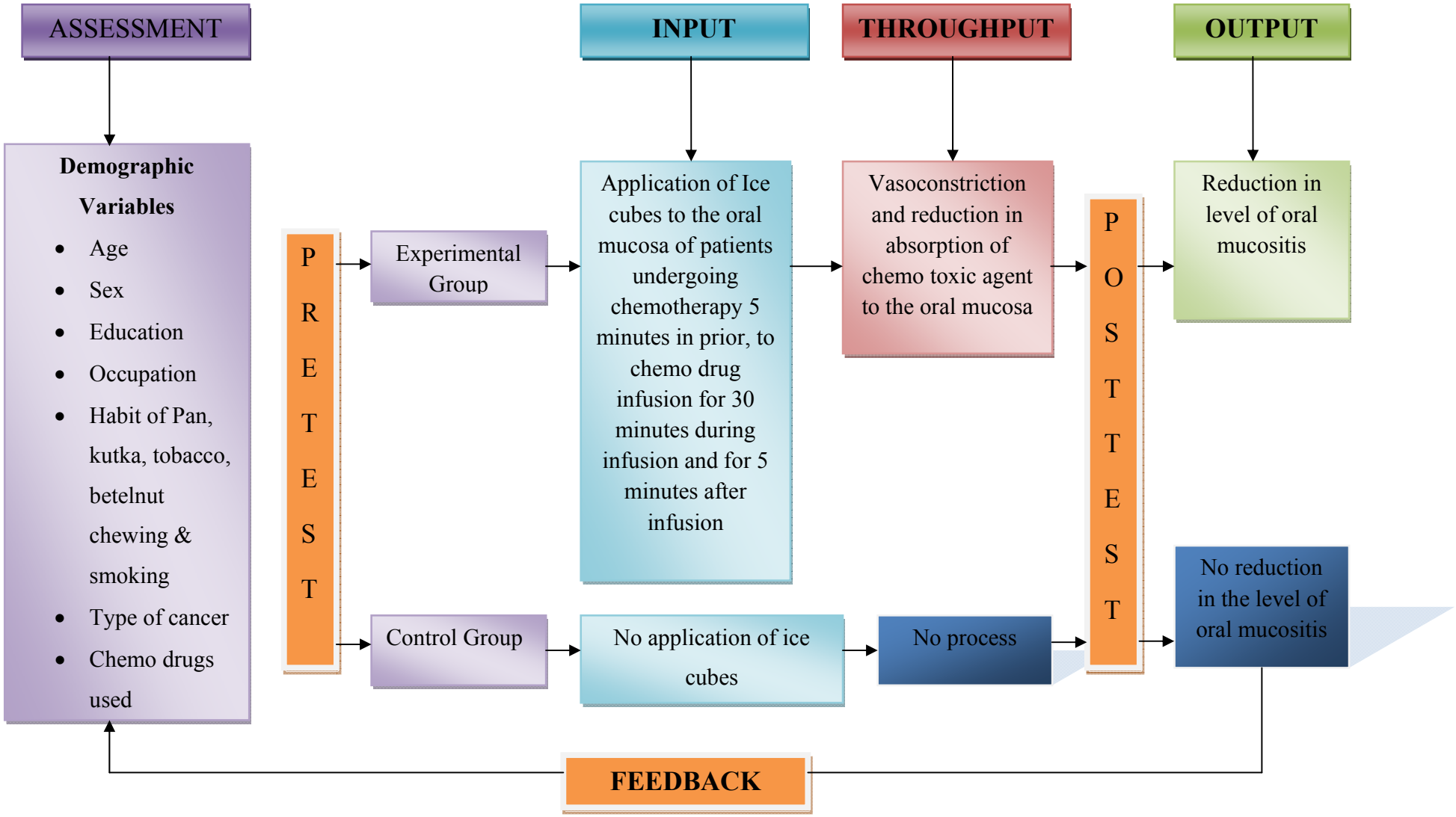
Output refers to the matter, energy and information that are processed.

In this study it refers to the reduction in the level of oral mucositis after application of ice cubes in the oral mucosa, measured by Oral Mucositis Assessment Scale.

FEEDBACK

After processing the input, the system sends output (matter, energy and information) to the environment in altered state. In this study it refers on the analysis of post test oral mucositis hence, when there is no reduction in the level of oral mucositis, then reassessment to be done from the assessment.

FIG 1: CONCEPTUAL FRAMEWORK BASED ON J.W. KENNEY'S OPEN SYSTEM MODEL



CHAPTER - II

REVIEW OF LITERATURE

According to Nancy Burns (2006) , the review of relevant literature is conducted to generate a picture of what is known about a particular situation and knowledge gaps that exist in it.

The Literature is classified under the following Headings:

1. Literature related to incidence of oral mucositis
2. Literature related to effects of oral mucositis
3. Literature Related to Scales Measuring Oral Mucositis:
4. Literature related to effectiveness of cryotherapy

Incidence of oral Mucositis:

Sankaranarayanan and Boffetta in their Research on cancer prevention, detection and management in low- and medium-income countries , (2010), stated that cancer is no longer the burden of high income countries. In 1970, 15 % of newly reported cases were in low and middle income countries (LMIC), compared with 56% in 2008, expected to rise to 70% in 2030. Almost two thirds in 7.6 million annual cancer deaths worldwide occur in low income countries, making it leading cause of mortality. The inquiry of cancer care is farther demonstrated by the case fatality from cancer, which is 75% in low income countries, referring to the fact that LMIC account for almost 80% of the burden of the disease due to cancer, yet receive only 5% of global resources devoted to deal with this emerging challenge. The congress decided to focus on primary prevention, screening and early detection, treatment and management, supportive care,

end of life as well as on how programme, infrastructures and resources are integrated into existing delivery system.

Oral mucositis is defined as mucositis of the oral and oropharyngeal mucous membranes and includes mucositis of the lips, tongue, gingiva, buccal mucosa, palate and floor of the mouth (Douherty & Bailey 2008). Oral mucositis, a condition characterised by inflammation and ulceration of the mouth with pseudomembrane formation, affects more than 40.0% of patients receiving chemotherapy and/or radiotherapy (Naidu, Ramana, Rani, Mohan, Suman & Roy 2004; Volpato, Silva, Oliveira, Sakai & Machado 2007).

Oral mucositis is a significant problem in patients undergoing chemotherapeutic management for solid tumors. In one study, it was reported that 303 of 599 patients (51 %) receiving chemotherapy for solid tumors or lymphoma developed oral and/or GI mucositis. Oral mucositis developed in 22% of 1236 cycles of chemotherapy, GI mucositis in 7% of cycles and both oral and GI mucositis in 8% of cycles. An even higher percentage (approximately 75–80%) of patients who receive high-dose chemotherapy prior to hematopoietic cell transplantation develop clinically significant oral mucositis. (Rajeshlalla, sonis, Peterson, 2008)

Fig : 1 – Level of Oral Mucositis

Fig 2: Ulcerative oral mucositis of the labial mucosa and floor of the mouth, buccal mucosa, lateral and ventral surfaces of the tongue.

Source : emedicine.medscape.com/article/1079570-clinical#a0217 ,(2013)

According to James Olimpio,(2008), Oral mucositis results in inflammatory cascade of complex interactive process that lead to painful break downs in the natural barrier state. Erythema, ulcerations, bleeding and breakdown of cellular and matriceal structures follow with the loss of the ability to prevent pathogenic bacteria from invading the mouth and, ultimately the blood stream in profoundly immuno suppressed patients. Toxic effects include painfull membranes with ulceration, inadequate nutrition from poor intake and absorption of nutrients, psychosocial distress, and potentially life threatening infection.

Literature related to effects of oral mucositis

According to news.cancerconnect.com (2014)., It is important that cancer patients be on the lookout for signs of mucositis, which should be treated as soon as possible once diagnosed. The consequences of mucositis can be mild, requiring little intervention, but they can also be severe--such as hypovolemia, electrolyte abnormalities, and malnutrition--and even result in fatality. Oral mucositis can:

- Cause pain
- Restrict oral intake
- Act as a portal of entry for organisms
- Contribute to interruption of therapy
- Increase the use of antibiotics and narcotics
- Increase the length of hospitalization
- Increase the overall cost of treatment.

Patients with oral mucositis and neutropenia (a type of white blood cell deficiency) have a relative risk of septicemia (a systemic, toxic illness caused by the invasion of the bloodstream

by virulent bacteria coming from a local infection) more than 4 times that of patients with neutropenia only.

According to www.oralcancerfoundation.org, (2012)., Mucositis is further complicated by the nausea and vomiting that often occur with treatment. Chemotherapy and radiation therapy can affect the ability of cells to reproduce, slowing healing of the oral mucosa, often extending the duration of present mucositis. Patients with damaged oral mucosa and reduced immunity are also prone to mouth infections.Taste loss tends to increase in proportion to the aggressiveness of treatment. Nausea, pain, vomiting, diarrhea, a sore or dry mouth may make eating difficult. Thus, maintaining adequate nutrition is an important challenge for oral cancer patients. Reduction of caloric intake can lead to weight loss, loss in muscle mass strength and other complications, including a decrease in immunity and a longer healing time from treatments.

RajeshLalla, conducted a study in National institute of health, (2008)., the findings revealed that the oral mucositis can be very painful and can significantly affect nutritional intake, mouth care, and quality of life. For patients receiving high-dose chemotherapy prior to hematopoietic cell transplantation, oral mucositis has been reported to be the single most debilitating complication of transplantation. Infections associated with the oral mucositis lesions can cause life-threatening systemic sepsis during periods of profound immunosuppression . Moderate to severe oral mucositis has been correlated with systemic infection and transplant-related mortality. In patients with hematologic malignancies receiving allogeneic hematopoietic cell transplantation, increased severity of oral mucositis was found to be significantly associated with an increased number of days requiring total parenteral nutrition and parenteral narcotic therapy, increased number of days with fever, incidence of significant infection, increased time in hospital and increased total inpatient charges .

Saba Bashtawi , (2013), stated that oral mucositis has a serious impact on those who are undergoing cancer treatment. Brown, (2010)., described tha oral mucositis the affects the treatment schedule by delay or discontinued treatment, and quality of life and aspects of daily living. Svanberg, (2007) stated that oral mucositis increases the possibility of the use of a nasogastric tube or total parenteral nutrition, the need for vascular access, and the use of Opioids. Rubenstein et al., (2004) stated that oral mucositis increases the length of hospital stay and consequently increases costs. Thus, OM represents a significant source of morbidity after chemotherapy and radiation therapy.

According to Dent Clin North (2008), In patients receiving chemotherapy for solid tumors or lymphoma, the rate of infection during cycles with mucositis was more than twice that during cycles without mucositis and was directly proportional to the severity of mucositis . Infection-related deaths were also more common during cycles with both oral and GI mucositis. In addition, the average duration of hospitalization was significantly longer during chemotherapy cycles with mucositis. Importantly, a reduction in the next dose of chemotherapy was twice as common after cycles with mucositis than after cycles without mucositis . Thus, mucositis can be a dose-limiting toxicity of cancer chemotherapy with direct effects on patient survival.

Literature Related to Scales Measuring Oral Mucositis:

According to European Society for Medical Oncology (ESMO) clinical practice guidelines. A wide variety of scales have been used to record the extent and severity of oral mucositis in clinical practice and research. The World Health Organization (WHO) scale is a simple, easy to use scale that is suitable for daily use in clinical practice. This scale combines both subjective and objective measures of oral mucositis.The National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 3.0 includes separate

subjective and objective scales for mucositis .The Oral Mucositis Assessment Scale (OMAS) is an objective scale, suitable for research purposes, that measures erythema and ulceration at nine different sites in the oral cavity. This scale has been validated in a multi-center trial with high inter-observer reproducibility and strong correlation of objective mucositis scores with patient symptoms . The Eastern Cooperative Oncology Group (ECOG) common toxicity criteria are also used in oncology trials to document severity of oral mucositis.

Literature related to effectiveness of cryotherapy

Researchers from the Fred Hutchinson Cancer Research Center, (2006), recently conducted a clinical trial to evaluate the effectiveness of ice chips to prevent or reduce OM in patients treated with high doses of Alkeran. This trial included 40 patients with multiple myeloma. Twenty-one patients received ice chips (cryotherapy) 30 minutes prior to treatment and continued to use the ice chips for six hours. Nineteen patients received normal saline instead of ice chips. Severe OM occurred in 14% of patients treated with ice chips, compared with 74% of patients treated with saline.Individuals treated with ice chips received fewer narcotics and nutrition through a vein than those treated with saline.

Mahood, Dose, Loprinzi, (1991).conducted a study on oral mucositis, they described that, mucositis is a significant dose-limiting toxicity associated with fluorouracil (5FU), particularly when it is combined with leucovorin. They hypothesized that oral cryotherapy would cause local vasoconstriction and would temporarily decrease blood flow to the oral mucous membranes. If cryotherapy were used during the time of peak serum 5FU levels, then the oral mucous membranes would have less exposure to 5FU and thus develop less mucositis. To test this hypothesis, 95 patients scheduled to receive their first cycle of 5FU plus leucovorin were randomized to have oral cryotherapy at the time of chemotherapy administration or to serve as a

control group. Subsequent mucositis was significantly reduced in the group assigned to receive cryotherapy as judged by the attending physicians (P = .0002) and by the patients themselves (P = .0001). We now routinely recommend this cryotherapy procedure for our patients receiving daily bolus 5FU plus leucovorin

Cryotherapy is the use of ice chips and ice cold water for the prevention of oral mucositis. Patients are to suck on ice and hold ice cold water in their mouth prior to, during and after rapid infusions of mucotoxic agents with a short half life. Cryotherapy is based on the theoretical and conceptual model of vasoconstriction decreasing exposure to the oral cavity mucous membranes to the mucotoxic agents. (Rubenstein, Peterson, and Schubert, 2004).

oral cryotherapy makes an important contribution to the protection of the oral health by reducing the mucositis score. In relevance to clinical practice, aggressive cancer therapy places patients at greater risk for oral complications and treatment related consequences. Oral cryotherapy, the therapeutic administration of cold, is a prophylactic measure for oral inflammation. The relevance for clinical practice will be understood the context of mucositis. The difference between the study and control group in terms of the change in PH values after chemotherapy was found to be statistically significant ($p<0.05$). Sue Nikoletti ., (2005)

Mustafa Baydar, Dikilitas, Sevine, Senel and Aydogdu, (2005), conducted the study that investigated the effects of local cryotherapy on mucositis incidence administerd during 5-Fu treatment. Mucositis developed in 6.7% of the courses given with cryotherapy. In courses without cryotherapy, the ratio was 38.9%. Hence the study concluded that, cryotherapy was promising in preventing mucositits due to 5-Fu based chemotherapy regimens.

Karagozoglu and Filiz Ulusoy, (2005), described that cryotherapy has effectively attenuate the onset and severity of mucositis in patients undergoing bolus chemotherapy with 5-Fu and melphalan.

Cryotherapy has been used to prevent or reduce oral mucositis in patients receiving bolus doses of 5-FU. Patients should place ice chips in the mouth 5 min before initiating chemotherapy and continue this procedure for about 30 min. It is believed that the decrease in oral mucosal temperature leads to local vasoconstriction, thereby, preventing the chemotherapeutic agent to reach the oral tissues in large quantities. This reduces the amount and severity of oral mucositis. Cryotherapy has also been shown to reduce oral mucositis when other chemotherapeutic agents with a short serum half-life like edatrexate are used. In this study, it was shown that only two out of 18 patients developed grade 2 or 3 mucositis compared to six out of seven controls. A recent clinical trial confirmed this finding in 22 patients who received high does chemotherapy had experienced grades 3 and 4 mucositis. (Megliorti, Edwards and Schubert, 2006),

The application of ice chips (cryotherapy) on the inflammed mucosa is based on the hypothesis that temporary local vasoconstriction of the oral mucosa vessels could reduce exposure of the replicating epithelium cells to peak levels of some cytostatic agents (Daniela alterio, 2007)

The Oncology Nursing Society Putting Evidence into Practice, (2007), team found that mucositis may be prevented with cryotherapy, the application of ice chips or ice-cold water to the oral cavity before, during, and after rapid infusions of mucotoxic agents. The literature supports cryotherapy for patients receiving bolus 5-fluorouracil (Multinational Association of Supportive Care in Cancer, 2005) and high-dose melphalan (Lilleby et al., 2006; Mori et al., 2006). Cryotherapy is not to be used with agents that require patients to be careful with exposure

to cold (e.g., oxaliplatin), and other agents require further study. The optimal duration and intensity of cryotherapy are not established, but patients generally hold ice or ice-cold water in their mouths for at least five minutes before, during, and 30 minutes after treatment.

To conclude oral cryotherapy makes an important contribution to the protection of oral health. Because of its case of application, tolerability, and lack of side effects makes it an important resource for reducing the incidence and severity of oral mucositis. The role of oncology nurses is crucial to the application and success of oral cryotherapy.

CHAPTER - III

RESEARCH METHODOLOGY

RESEARCH APPROACH: Quantitative approach was used for this study.

Quantitative approach is the numeric information that is obtained from a formal measurement and is analysed statistically.(polit, 2011)

RESEARCH DESIGN:

True experimental Pre-test post-test control group design was adapted.

An experimental design in which data are collected from subjects both before and after introducing intervention.(polit, 2011)

Group	Pretest	Intervention	Post test(3rd day)	Post test(21st day)
Experimental	O1	X	O2	O3
Control	O1	-	O2	03

Keys:

O1 – pre – test level of oral mucositis among experimental group and control group on 1st day

O2 – post – test level of oral mucositis among experimental group and control group on 3rd day

O3 – post – test level of oral mucositis among experimental group and control group on 21st day

X – administration of flavored ice cubes among experimental group

DEPENDENT VARIABLE:

Flavored ice cubes

INDEPENDANT VARIABLE:

Oral Mucositis

RESEARCH SETTING:

Study was conducted in Devaki Cancer and Research Institute, Arasaradi, Madurai, which is 7.6 Km away from sacred heart nursing college. This hospital provides all specialised care for all types of cancer and cancer patients on inpatient and out patient basis. The treatment includes chemotherapy and radiation therapy -brachy therapy, and tele therapy with the help of linear accelerator therapy .

POPULATION:

The target population of this study was patients with cancer undergoing chemotherapy infusion of cisplatin + 5Fu,cisplatin + etoposide, cisplatin + paclitaxel ,cisplatin + irinotecan, cisplatin + gemcitabine, for 3 days.

SAMPLE:

Patients with cancer receiving chemotherapy and who fulfills the inclusion criteria were the samples.

SAMPLE SIZE:

Total sample size was 60, among whom, 30 in experimental group received application of flavored ice cubes, and 30 in control group received no intervention.

SAMPLING TECHNIQUE:

Simple random sampling – lottery method was used to allot the patients to experimental group and control group.

Lottery method is that, each member of the population is assigned to a unique number. The blind-folded researcher picks numbered tags from the bowl or hat that is mixed

thoroughly.all the individuals bearing the numbers picked by the researcher are the subjects for the study.(Suresh.k.sharma).

CRITERIA FOR SAMPLE SELECTION

INCLUSION CRITERIA

- Patients with cancer in agegroup of 20 -70 years
- Patients with cancer who are undergoing chemodrug infusion of combinations like cisplatin + 5Fu,cisplatin + etoposide, cisplatin + paclitaxel ,cisplatin + irinotecan, cisplatin + gemcitabine, for 3 days.
- Patients who had ulceration of score 1-18 and erythema of score 1-9.as per Oral mucositis Assessment Scale.
- Both male and female patients with cancer
- Those Who were willing to participate.

EXCLUSION CRITERIA:

- Patients with cancer who underwent oral surgery
- Patients with cancer having diabetes mellitus
- Patients with cancer who has severe oral mucositis

RESEARCH TOOL AND TECHNIQUE

The instrument used for the study has two parts

Section I: Demographic profile

It consists of demographic profile such as age, sex, education, occupation, habits of smoking, tobacco chewing, kutka and panmasala chewing.

Section II: Clinical profile

Type of cancer, chemo drugs used.

Section III:

This part consists of oral mucositis assessment scale. It is standardized tool, downloaded from the internet The tool has nine items in it. The nine items will be assessed in two different criteria as ulceration and erythema, each items were scored between 0, 1, 2 and 3

In ulceration,

0 refers to no ulceration,

1 indicate < 1 cm,

2 indicates ulcer size ranging from 1 – 3 cm,

3 indicates ulcer above 3 cm.

In erythema,

0 refers to no erythema,

1 refers to non-severe erythema,

2 refers to severe erythema,

Based on the scores obtained, the subjects will be grouped into various categories.

The tool is annexed in appendix IV.

Score between,

In ulceration

1 – 9 falls under mild ulceration,

10 – 18 – moderate ulceration,

19 – 27 – severe ulceration

In erythema

1 – 9 – not severe

10 – 18 – severe erythema.

Intervention:

Preparation of flavored ice cubes:

Milk – 300 ml.

Sugar -1 ½ table spoon

Vanilla – 1 ½ tea spoon

Freezing time – 8-12 hours

Ice cubes were carried to the patient side using cool box.

Intervention	Rationale
In this study, patients undergoing 3days chemo drug infusion for cancer at every 21 days interval are selected as the experimental group on the counts of inclusion criteria and exclusion criteria.	Development of oral mucositis is very rapid in patients undergoing 3days infusion of chemo drug .
The oral mucositis of the patient was assessed by oral mucositis assessment scale(OMAS scale)	It is a standard tool that helps to evaluate the extent of mucositis.
• The oral mucosa is examined on the first day of infusion. Before the infusion of infusion of combinations like cisplatin + 5Fu,cisplatin + etoposide, cisplatin + paclitaxel ,cisplatin + irinotecan, cisplatin + gemcitabine, for 3 days.	Pre – test : evaluates the oral mucosal status
For experimental group Ice cubes are applied to every parts of the mouth for 20 – 30 minutes. After the chemodrug infusion, the patients were asked to do the same for 5 minutes.	Inorder that every part of the **Cryotherapy reduces the amount of drug reaching the oral mucous membrane** and may therefore reduces the mucositis caused by the cytotoxic effects of the drugs.

After completion of one ice cube it will be replaced by the other. Post test was done on 3rd day and 21st day of the chemo cycle using oral mucositis assessment scale.	Maintains the constancy of coolness within the mouth. Helps to know the effectiveness of oral cryotherapy in reduction of oral mucositis.

TESTING OF THE TOOLS:

Validity:

The validity of the tool and intervention was obtained by giving it to seven experts, two Medical oncologists and four Medical surgical nursing experts and one Bio-statistician. Based on their valid suggestions reframing of the intervention was done.

Reliability:

Oral mucositis assessment scale demonstrated a good reliability of 0.88 on the inter rater method.

Pilot study:

Among six patients each three were assigned to experimental group and control group. Data were analysed and findings revealed that the study was feasible.

Data collection procedure:

Formal permission was obtained to conduct the study from the clinical oncologist in Devaki Cancer and Research Institute, Madurai and from the ethical committee of Sacred Heart Nursing College, Madurai .The researcher introduced to the selected sample &the verbal consent obtained from each subject after giving assurance of confidentiality. The period of study extended for 6weeks.The data was collected from Monday –Saturday. The samples were selected according to the criteria laid down.

Monday – Saturday (9a.m to 5 p.m)						
Pre test (Day 1) & Post test – I (Day 3)				Post test - II (Day 21)		
Weeks	**I**	**II**	**III**	**IV**	**V**	**VI**
Groups Experimental	14	9	7	14	9	7
Control	10	12	8	10	12	8

On day-1 the samples who had mild to moderate level of oral mucositis score ,and patients who fulfilled the inclusion &exclusion criteria were allowed for application of ice cubes. The ice cubes were made by the mixture of water, milk, sugar &vanilla essence (to add color & flavor). The application of ice cubes had been started by the researcher 5 minutes prior to the chemo drug infusion and continued for 30 minutes and 5 minutes after the chemo drug infusion for 3 days .These steps were followed in all the samples , under experimental group .The samples co-operated well , and participated actively in the study.

At the end of 3$^{rd\ day}$ of chemo drug infusion and on 21st day of return of next chemocycle the oral mucositis was assessed and scored, using Oral Mucositis Assessment Scale.

In control group the level of oral mucositis was assessed using oral mucositis assessment scale 1st ,2nd and 3rd day of the chemocycle. The control group underwent their treatment regimen with no intervention of oral cryotherpay.

Plan for data analysis:

The data analysis of the study of the study was done according to the objectives of the study by using inferential and descriptive statistics.

Descriptive statistics:

Frequency, percentage and mean were used for the analysis of level of oral mucositis.

Inferential statistics:

Paired ‘t’ test were used to determine between the prettest and post test in terms of the effectiveness of application of ice cubes in experimental group.

Independent ‘t’test was used to determine the difference between the post-test of experimental group and control group in terms of effectiveness of application of ice cubes.

Chi square was used to determine the association between selected demographic variables.

Protection of human rights:

Research proposal was approved by dissertation committee of Sacred heart Nursing College, Madurai. Permission was obtained from Devaki Cancer and Research Institute, Madurai, prior to the study. Oral consent of each study subject was obtained before starting data collection. Assurance was given to the subjects, that confidentiality was maintained. The subjects were explained that they have rights to withdraw from the study. There was absence of physical and psychological strain to study subjects.

CHAPTER – IV

ANALYSIS AND INTERPRETATION OF DATA

This chapter deals with the description of samples, classification, analysis, and interpretation of data collected to evaluate the achievement of the objectives of the study and discussion of the study findings, the data is tabulated and described as follows.

Presentation of the findings of the study

Section 1:

1. Frequency and distribution of subjects with regard to the selected demographic variables.
2. Frequency and percentage distribution of the subject with regard to selected clinical variables.

Section 2:

3. Distribution of subjects according to the level of mucositis before and after application of ice cubes in experimental group
4. Distribution of subjects according to the level of mucositis in control group
5. Distribution of subjects according to the post test level of oral mucositis in experimental group and control group

Section 3:

6. Comparison of mean pre test and post test level of oral mucositis in experimental group on day 3
7. Comparison of mean pre test an post test level of oral mucositis among the patients receiving chemotherapy after the application of flavored ice cubes in experimental group on day 21.

8. Comparison of mean post test of oral mucositis on day 3 and on day 21 in the experimental group
9. Comparison of mean pre test and post test (day 21) level of oral mucositis in control group
10. Comparison of mean post test level of oral mucositis of the experimental group an control group on day 3.
11. Comparison of mean post test level of oral mucositis of the experimental group an control group on day 21.

Section 4:

12. Association between the levels of oral mucositis of experimental group and control group before the use of flavored ice cubes with demographic variables.

SECTION – I

DEMOGRAHIC VARIABLES OF THE SAMPLES

This section deals with the demographic variables of the subjects such as age, sex, education status, occupation, type of cancer, habits of tobacco chewing, pan, kutka, smoking, and betel nut chewing.

Table 1: Frequency and distribution of subjects with regard to the selected demographic variables

Demographic Characteristics	Experimental Group n = 30		Control Group n = 30		Total N= 60	
	F	%	F	%	F	%
Age: (in years)						
➢ 20 – 30 years	2	6.66	2	6.66	4	6.66
➢ 31 – 40 years	7	23.33	5	16.66	12	20
➢ 41 – 50 years	5	16.67	6	20	11	18.33
➢ 51 – 60 years	11	36.67	10	33.33	21	35
➢ 61 – 70 years	5	16.66	7	23.33	12	20
Sex:						
➢ Male	21	70	16	53.33	37	61.66
➢ Female	9	30	14	46.66	23	38.33
Education:						
➢ Primary	9	30	6	20	15	25
➢ Secondary	6	20	11	36.66	7	28.33
➢ Higher Secondary	5	16.6	1	3.33	6	10
➢ Illiterate	10	33.33	12	40	22	36.66
Occupation:						
➢ Employed	20	66.66	22	73.33	42	70
➢ Unemployed	10	33.33	8	26.67	18	30

Table cont…

Demographic Characteristics	Experimental Group n = 30		Control Group n = 30		Total N= 60	
	F	%	F	%	F	%
Habits of tobacco chewing:						
➢ Yes	3	10	1	3.33	4	6.66
➢ No	27	90	29	96.6	56	93.33
Habit of betel nut chewing:						
➢ Yes	2	6.66	1	3.33	3	5
➢ No	28	93.33	29	96.6	57	95
Habit of Smoking:						
➢ Yes	13	43.33	11	36.66	24	40
➢ No	17	56.66	19	63.33	36	60
Habit of Kutka:						
➢ Yes	0	0	0	0	0	0
➢ No	0	0	0	0	0	0
Habit of Pan:						
➢ Yes	2	6.66	1	3.33	3	5
➢ No	28	93.33	29	96.6	57	95

- With regard to age, both in experimental group and control group majority of samples were between 51-60 years ,11(36.67%) and 10(33.33%) respectively.
- Regarding sex, in both experimental group and control group the majority of the samples were males. 21(70%) and 16(53.33%) respectively.
- With regard to education both in experimental group and control group the majority of the samples were illiterate 10(33.33%) and 12 (40%) respectively.

- Wit regard to occupation both in experimental group and control group the majority of the samples were employed 20(66.66%) and 22(73.33%) respectively.
- Regarding the smoking habits 13(43.33%)of the samples in experimental group and 11(36.66%)of samples in control group had habit of smoking.

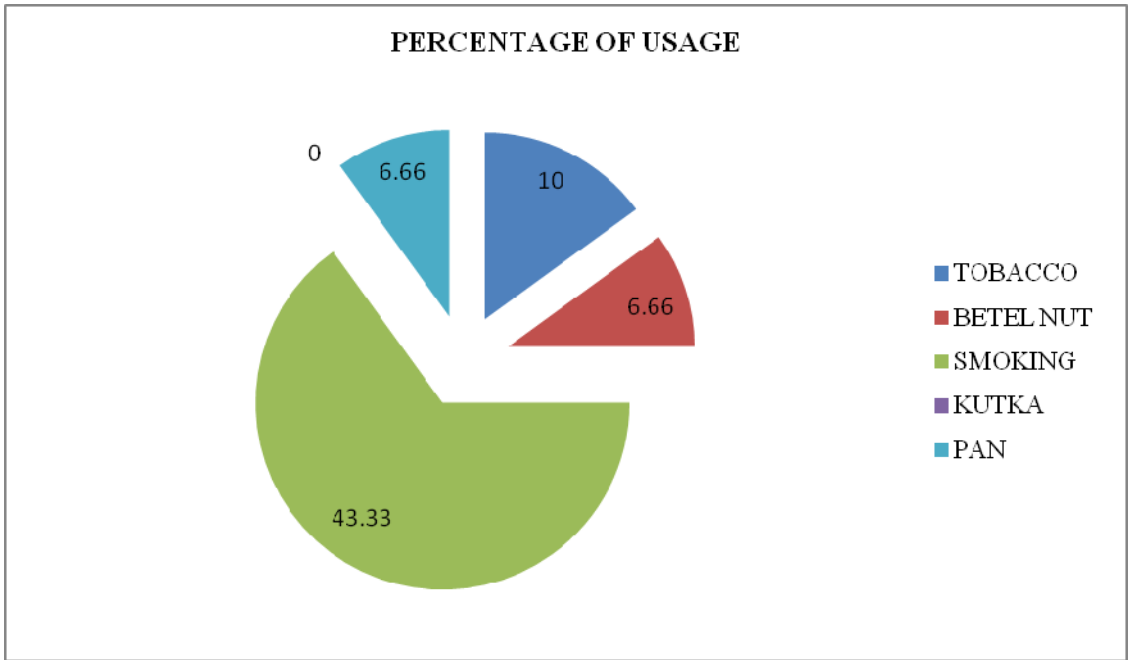


FIG 4: Pie diagram showing habits of samples on usage of tobacco, betelnut, kutka, pan masala chewing and smoking in experimental group.

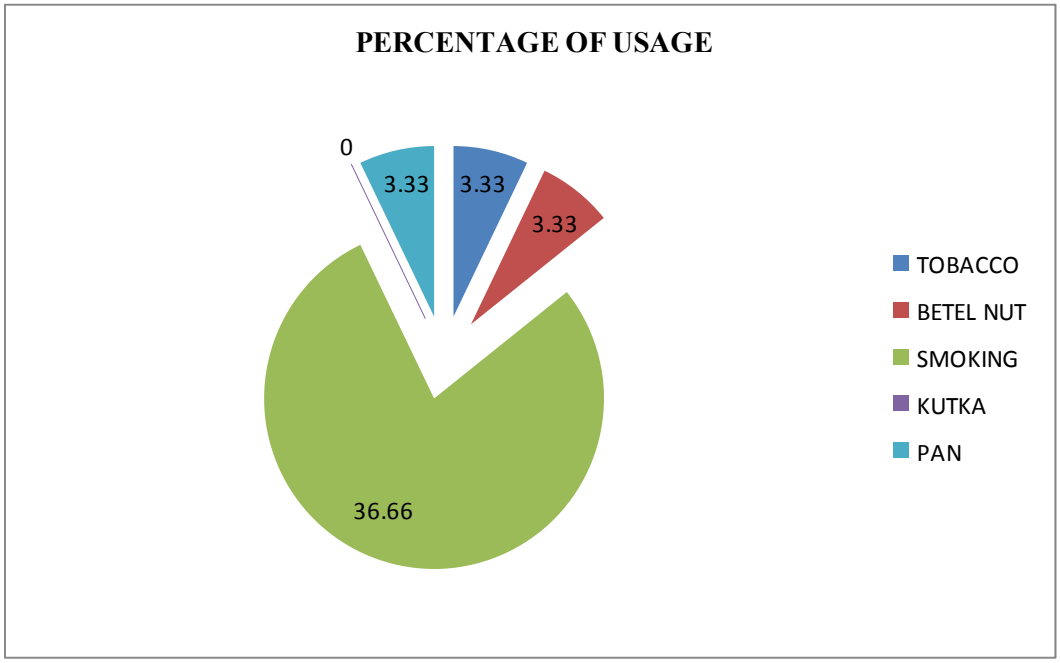


FIG 5: Pie diagram showing habits of samples on usage of tobacco, betelnut, kutka, pan masala chewing and smoking in control group.

Clinical Profile of the samples

This section deals with the clinical variables of the subjects.

Table 2: Frequency and percentage distribution of the subject with regard to selected clinical variables.

Demographic Characteristics	Experimental Group n = 30		Control Group n = 30		Total N= 60	
	F	%	F	%	F	%
Type of Cancer:						
➢ Lung Cancer	8	26.66	9	30	17	28.33
➢ Stomach Cancer	5	16.66	5	6.66	7	11.66
➢ Cervical Cancer	7	23.33	8	20	13	43.33
➢ Colon Cancer	0	0	1	3.33	1	1.66
➢ Rectal Cancer	1	3.33	2	6.66	3	5
➢ Overian Cancer	2	6.66	3	10	5	8.33
➢ Cricoid Cancer	2	6.66	0	0	2	3.33
➢ Hodgkins Lymphoma	1	3.33	1	3.33	1	1.66
➢ Cancer Skin	1	3.33	0	0	1	1.66
➢ Ca nasopharynx	1	3.33	0	0	1	1.66
➢ Ca Supraglottis	0	0	1	3.33	1	1.66
➢ Ca larynx	2	6.66	0	0	2	3.33
Drugs Used:						
➢ Cisplatin + 5FU	7	23.3	17	56.7	24	80
➢ Cisplatin + etoposide	16	53.3	6	20.0	22	73.3
➢ Others*	7	23.3	7	23.3	14	46.6

Regarding the type of cancer among experimental group 8(26.66%) were suffering with lung cancer and in control group 9(30%) were having lung cancer.

Regarding the usage of drug in experimental group 16(53.3%) of samples were treated with cisplatin+etoposide and in control group 17(56.7%) of samples were treated with cisplatin and 5fu combination.

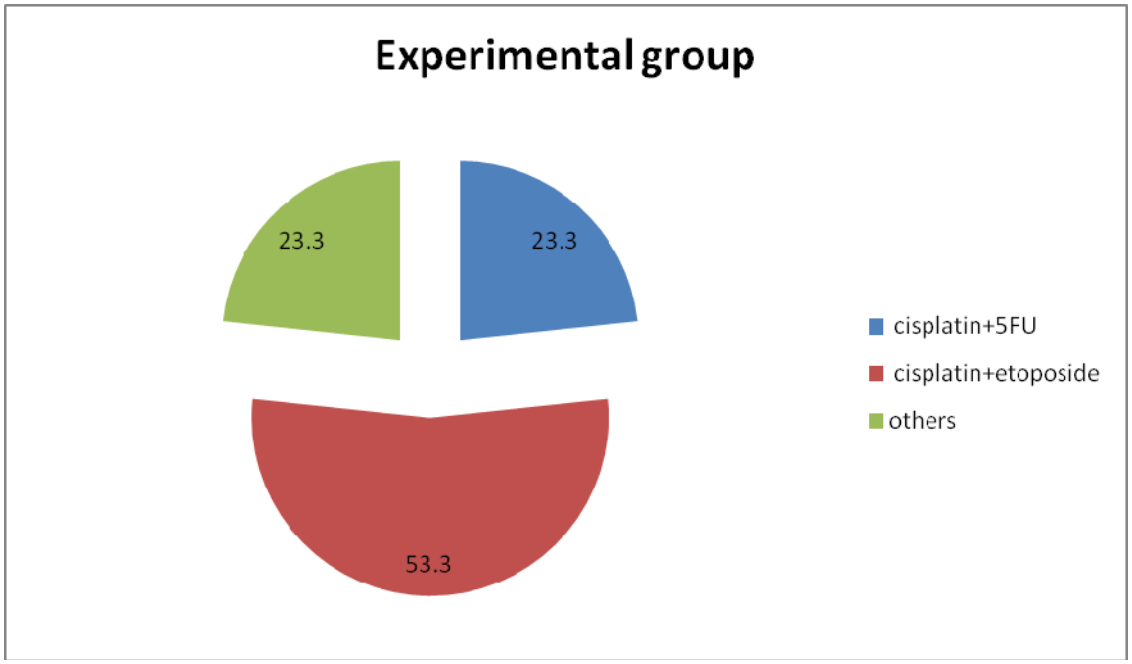


FIG 6: Pie diagram showing chemodrug usage among the experimental group with regard to selected demographic variables

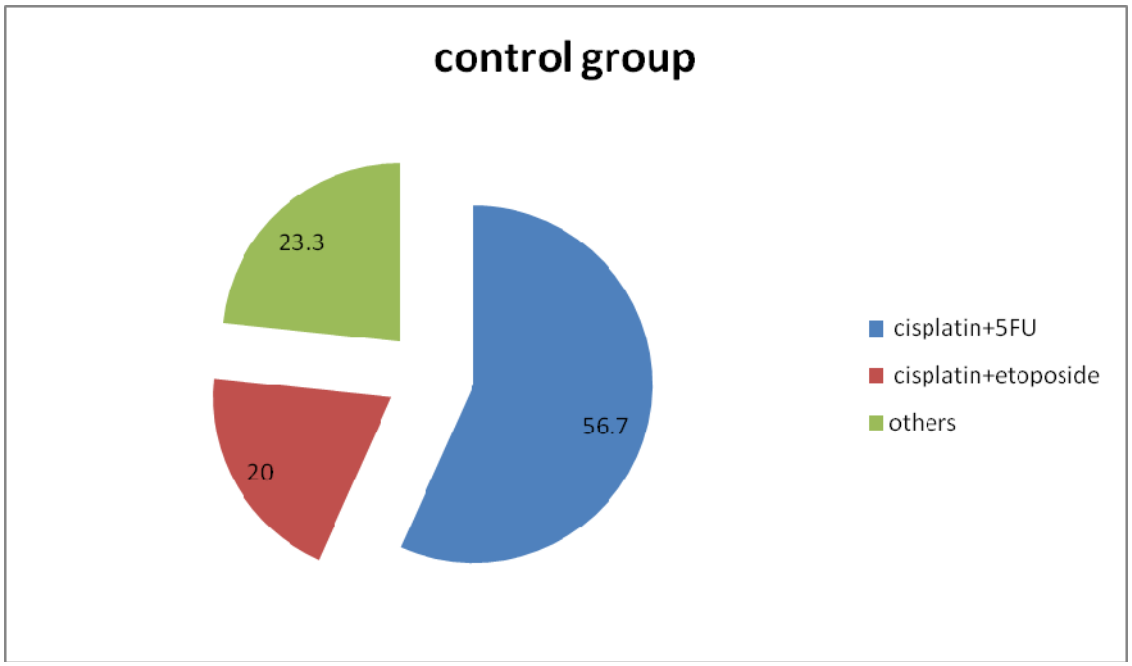


FIG7: Pie diagram showing chemodrug usage among the control group with regard to selected demographic variables

SECTION – 2

DISTRIBUTION OF SAMPLE ACCORDING TO THE LEVEL OF MUCOSITIS

Table 3: Distribution of subjects according to the level of mucositis before and after application of ice cubes in experimental group.

Level of Mucositis	Pre Test		Post Test			
	F	%	F (3rd day)	%	F (21st day)	%
Ulceration:						
➢ No ulcer	9	30	15	50	22	73.33
➢ Mild	21	70	15	50	8	26.6
Erythema:						
➢ No erythema	4	13.3	21	70	18	60
➢ Not severe	26	86.66	9	30	12	40

Data on table 3 are based on the level of mucositis obtained. The subjects were classified into 4 groups. No ulcer (0), mild (1-9), moderate (10-18), severe (18-30).

In experimental group Before using of application of flavored ice cubes client 9 samples(30%) had no ulcer and 21(70%) had mild ulceration. After application of ice cubes on 3rd day observation 15 (50%) had no ulceration and 15 (50%) had mild ulceration on 21st day observation in 22 (73.33%) had no ulceration and 8 (26.6%) had mild ulceration.

Regarding erythema 4(13.3%) of samples had no erythema and 26 (86.66%) had erythema of not severe category in pre test. After application of ice cubes on 3rd day 21(70%) had no erythema and 9(30%) had not severe erythema and on 21st day 18 (60%)of samples had no erythema and 12 (40%)of samples had not severe erythema. This difference may be due to application of ice cubes.

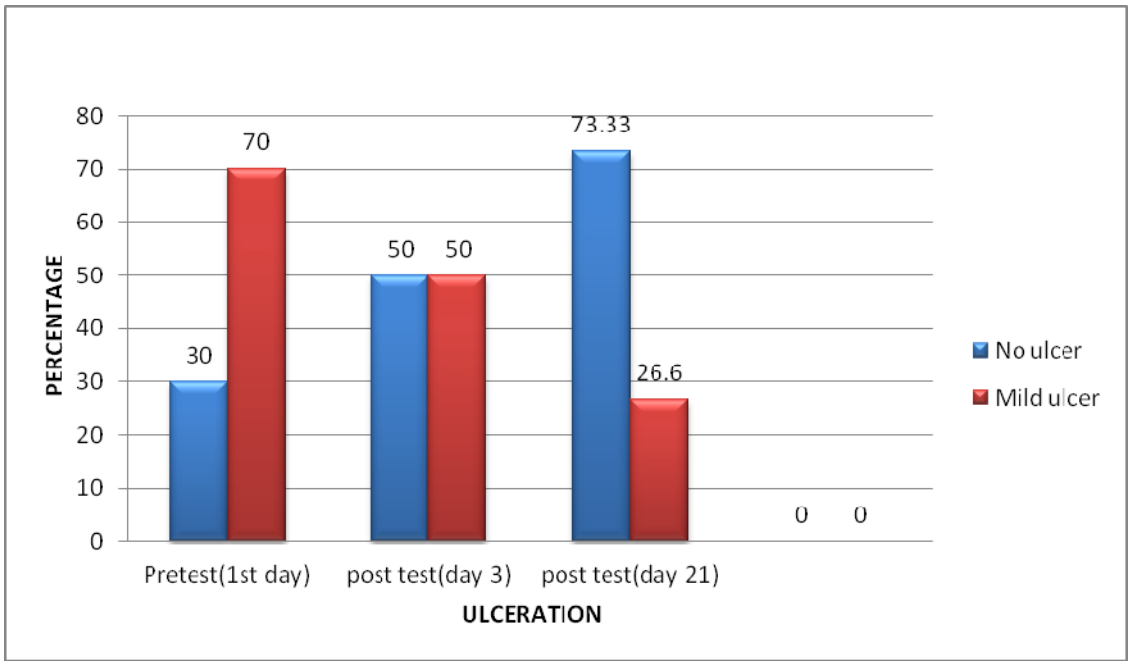


FIG 8 : Distribution of subjects according to the level of mucositis – ulceration in experimental group.

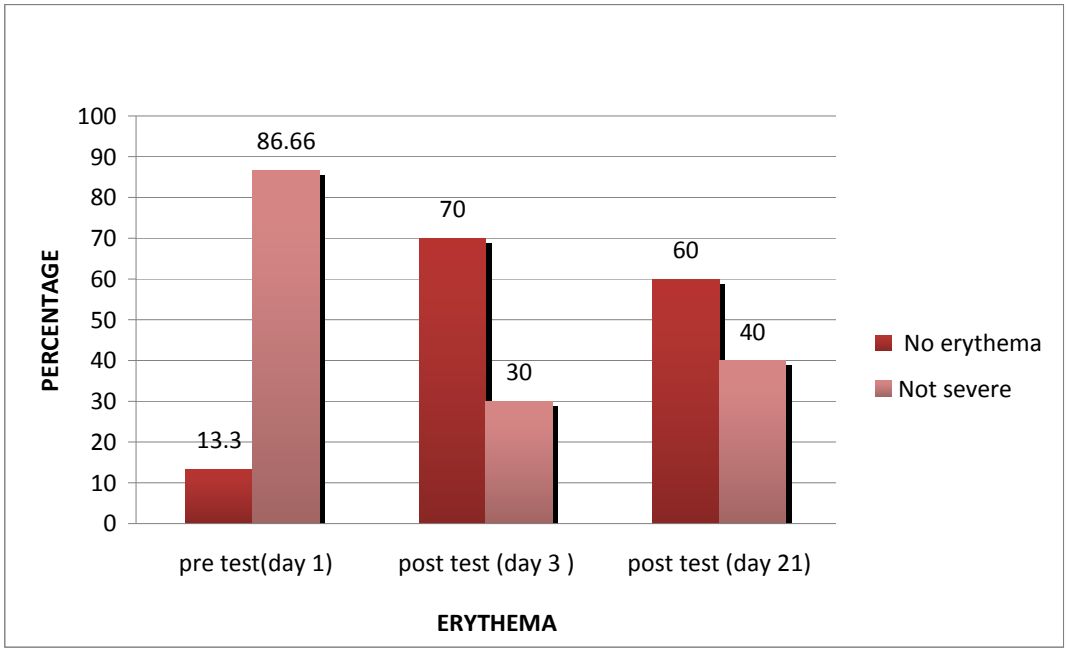


FIG 9: Distribution of samples according to the level of oral mucositis – erythema in experimental group.

Table 4: Distribution of subjects according to the level of mucositis in control group

Level of Mucositis	Pre Test		Post Test			
	F	%	F (3rd day)	%	F (21st day)	%
Ulceration:						
➢ No ulcer	8	26.66	3	10	9	30
➢ Mild	22	73.3	27	90	21	70
Erythema:						
➢ No erythema	12	40	1	3.33	2	6.66
➢ Not severe	18	60	29	96.66	28	93.33

Table 4 shows that 8(26.66%) of samples had no ulceration and 22(73.3%) had mild ulceration. On 3rd day observation 3 (10%) had no ulceration and 27 (90%) had mild ulceration on 21st day observation 9(30%) had no ulceration and 21(70%) had mild ulceration.

For erythema 12(40%) had no erythema and 18(60%) had not severe erythema and on 3rd day observation 1(3.33%) had no erythema and 29(96.66%) had not severe erythema and on 21st day observation 2(6.66%) had no erythema and 28 (93.33%) had not severe erythema.

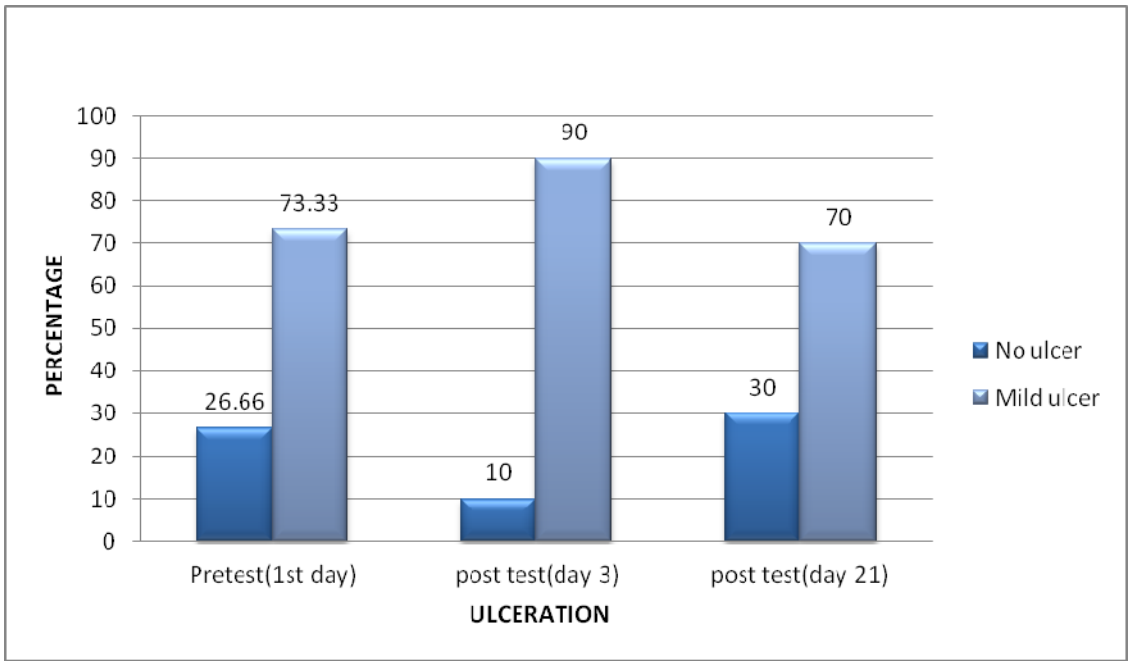


FIG 10: Distribution of subjects according to the level of mucositis – ulceration in control group

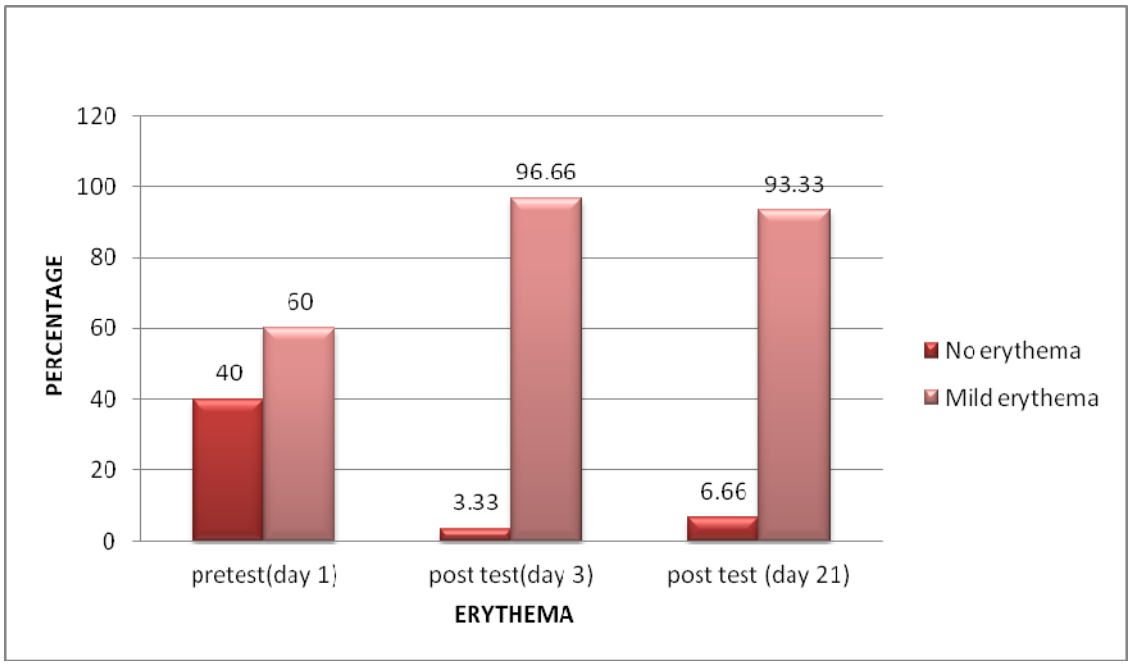


FIG 11: Distribution of subjects according to the level of mucositis – erythema in control group

Table 5: Distribution of subjects according to the post test level of oral mucositis in experimental group and control group.

Level of Mucositis	Experimental Group N = 30				Control Group N = 30			
	3rd day		21st day		3rd day		21st day	
	F	%	F	%	F	%	F	%
Ulceration:								
➢ No Ulcer	15	50	22	73.33	3	10	9	30
➢ Mild	15	50	8	26.66	27	90	21	70
➢ Moderate	-	-	-	-	-	-	-	-
➢ Severe	-	-	-	-	-	-	-	-
Erythema:								
➢ No erythema	21	70	18	60	1	3.33	2	6.66
➢ Not severe	9	30	12	40	29	96.66	28	93.33

* significant at 0.05 level.

Table 5 shows that in experimental group the 15(50%) of samples had n ulceration on 3rd day observation and on 21st day 22(73.33%) had no ulceration in control group on 3rd day (3)10% had no ulceration and 27(90%) had mild ulceration. On 21st day 9(30%) had no ulceration and 21(70%) had mild ulceration.

Regarding erythema in experimental group on 3rd day 21(70%) had no erythema and 9(30%) had not severe erythema and on 21st day observation 18(60%) had no erythema and 12(40%) had not severe erythema. In control group on 3rd day observation 1(3.33%) had no erythema and 29(96.6%) had not severe erythema. On 21st day 2(6.66%) had no erythema and 28(93.33%) had no severe erythema.

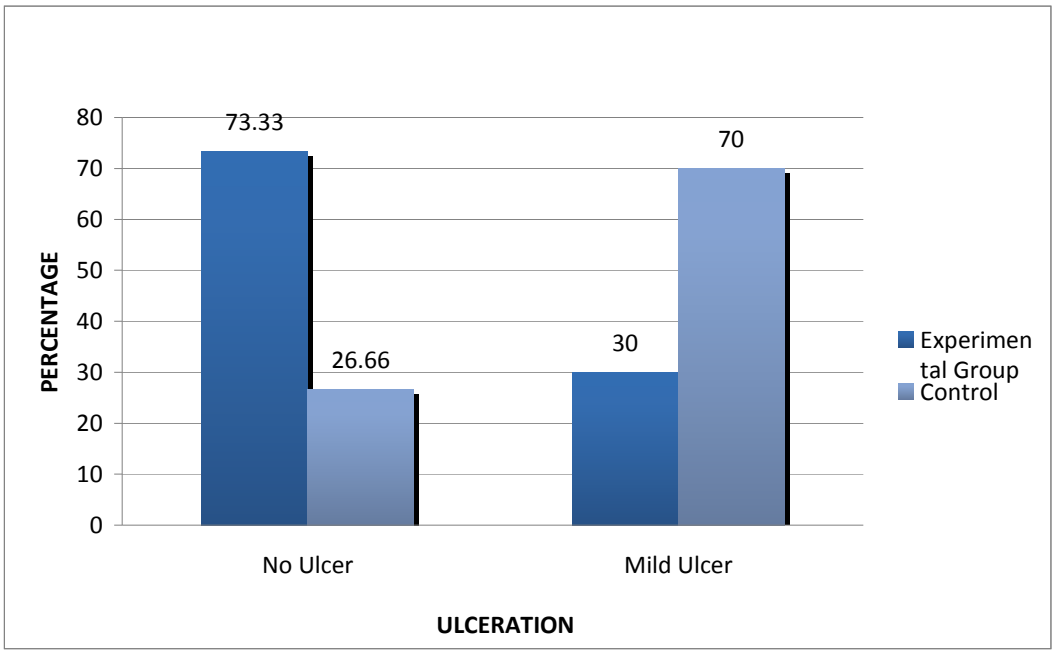


FIG 12: Distribution of subjects according to the post test level of oral mucositis on day 21 in experimental group and control group.

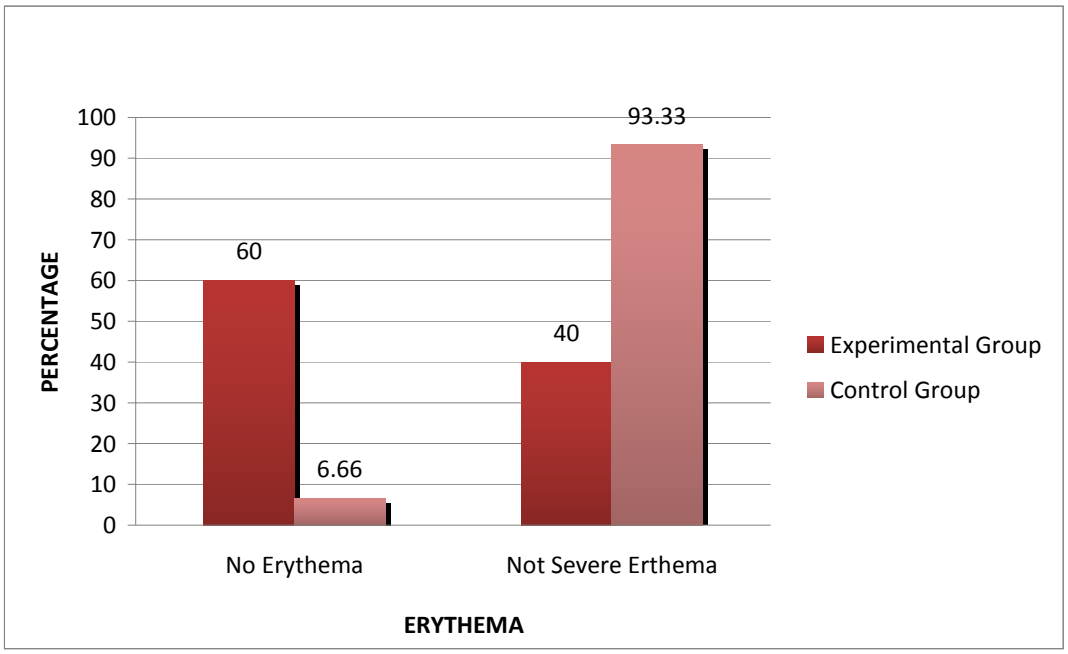


FIG 13: Distribution of subjects according to the post test level of oral mucositis on day 21 in experimental group and control group.

SECTION – 3

Table 6: Comparison of mean pre test and post test level of oral mucositis in experimental group on day 3.

Measurement	N	Mean	SD	T-test	Df
Pre test	30	2.76	3.10	5.67*	29
Post test	30	1.13	1.64		

* Significant at 0.05 level.

Table 6 shows that on 3rd day observation in experimental group the mean pre test score is 2.76 and the mean post test (3rd day) score is 1.13. The 't' value for 3rd day observation is 5.67 is statistically significant at 0.05 level. This indicates that the mean difference of 1.63 score of oral mucositis is a true difference and has not occurred by chance.

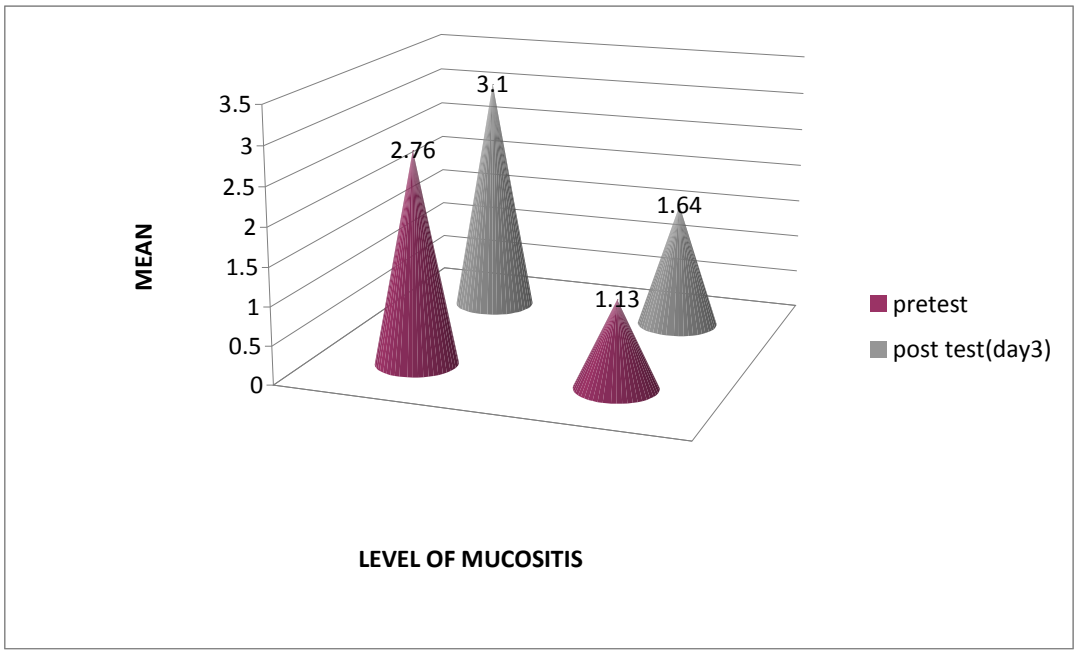


FIG 14 : Comparison of mean pre test and post test level of oral mucositis in experimental group on day 3

Table 7: Comparison of mean pre test and post test level of oral mucositis among the patients receiving chemotherapy after the application of flavored ice cubes in experimental group on day 21.

Measurement	N	Mean	SD	T-test	Df
Pre test	30	2.76	3.10	4.2*	29
Post test	30	0.76	0.83		

* Significant at the level of 0.05.

To find out if there is any difference between the mean mucositis score before and after application of flavored ice cubes, the null hypothesis was stated as follows.

H01: the mean post test level of oral mucositis score among the patients with cancer receiving chemotherapy who received application of flavored ice cubes will not be significantly lower than their mean pre test level of mucositis score in experimental group.

Table 8 shows that, the mean post test score (0.76) of level of mucositis after application of flavored ice cubes was lower than the mean pre test score of (2.76). the obtained 't' value of 4.2 at df 29 was significant at the level of 0.05. This indicates that the difference in mean is betterment of oral mucositis status of the samples. So, the researcher rejets the null hypothesis and accepts the research hypothesis.

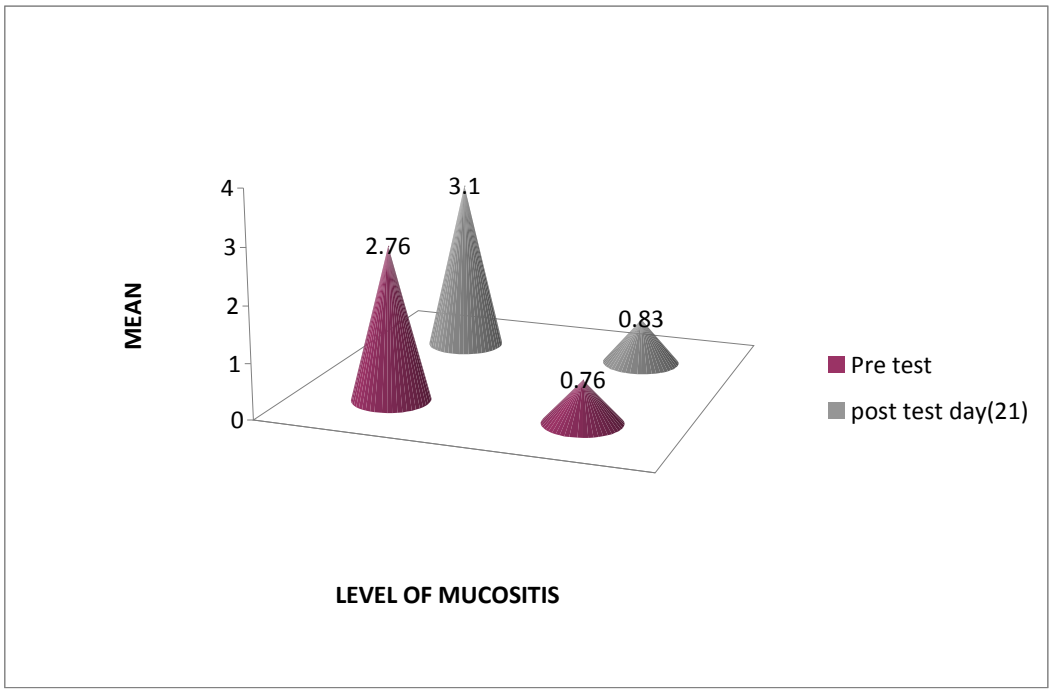


FIG 15: Comparison of mean pre test and post test level of oral mucositis in experimental group on day 21

Table 8: Comparison of mean post test level of oral mucositis on day 3 and on day 21 in the experimental group.

Measurement	N	Mean	SD	T-test	Df
Level of oral mucositis on day 3	30	1.13	1.64	2.91*	29
Level of oral mucositis on day 21	30	0.76	0.83		

Table 8 shows that the mean mucositis score of experimental group on 3rd day was 1.13 and the mean score on 21st day is 0.76. The t-value is 2.91 is statistically significant at 0.05 level. This indicates that the mean difference of 0.37 score of oral mucositis is a true difference and has not occurred by chance.

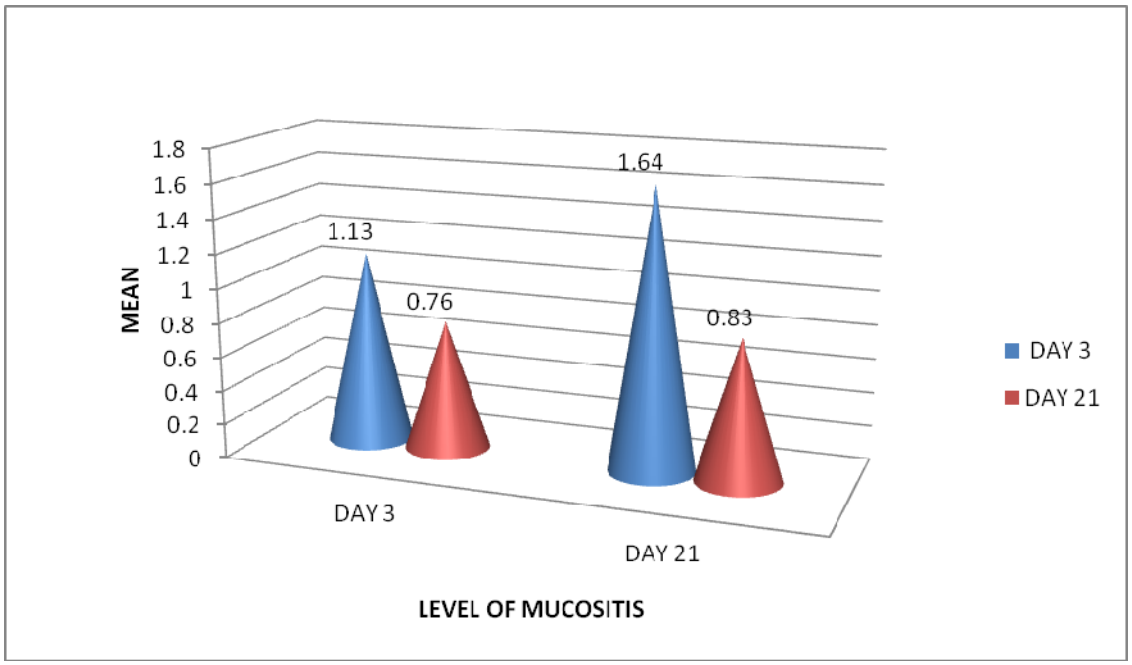


FIG 16: comparison of mean post test level of oral mucositis on day 3 and on day 21 in the experimental group.

Table 9: comparison of mean pre test level of oral mucositis and mean post test level of oral mucositis in control group.

Measurement	N	Mean	SD	T-test	Df
Pre test	30	2.63	2.15	4.23*	29
Post test day 21	30	2.36	1.66		

* Significant at the level of 0.05.

Table 9 shows that on 1st day observation in control group the mean pre test score is 2.63 and the mean post test (21st day) score is 2.36. The 't' value for 21st day observation is 4.23 is statistically significant at 0.05 level. This indicates that the mean difference of 0.33 score of oral mucositis is a true difference and has not occurred by chance.

Table 10: Comparison of mean post test level of oral mucositis of the experimental group and control group on day 3.

Measurement	N	Mean	SD	T-test	Df
Experimental Group	30	1.13	1.64	8.6*	29
Control Group	30	3.8	2.03		

The table 10 shows that the mean mucositis score on day 1 was 1.13 and score on day 3 was 3.8. The t-value is 8.6 is statistically significant at 0.05 level. This indicates that the mean difference of 2.67 score of oral mucositis is a true difference and has not occurred by chance.

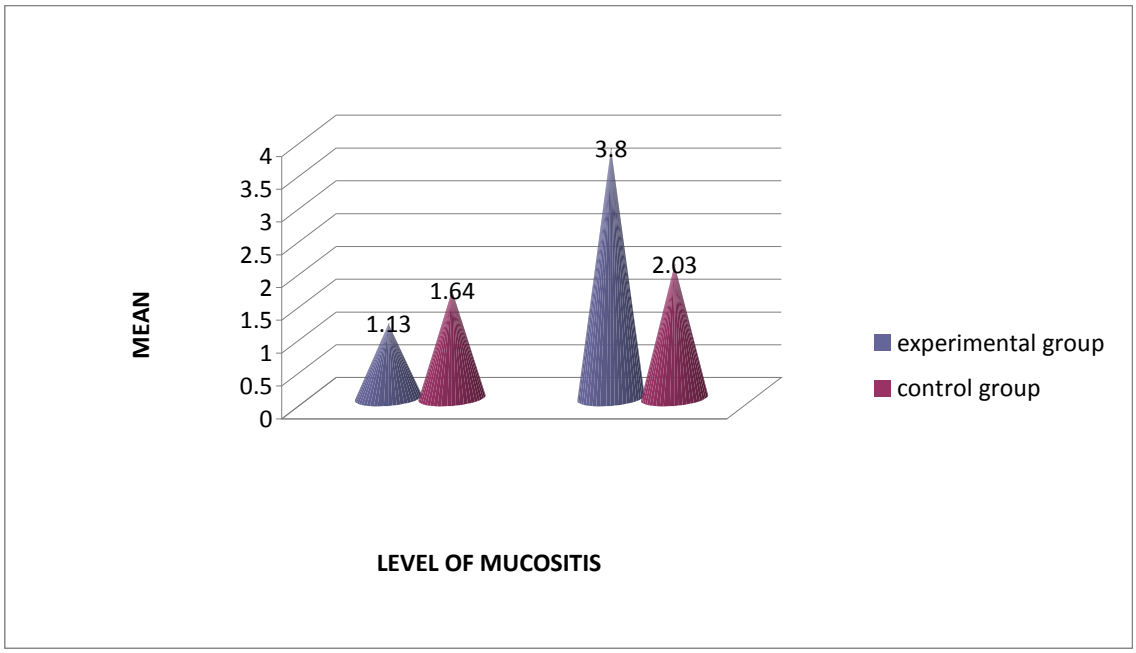


FIG 17: Comparison of mean post test level of oral mucositis of the experimental group and control group on day 3

.

Table 11: Comparison of mean post test level of mucositis of experimental group and control group on day 21.

Measurement	N	Mean	SD	T-test	Df
Experimental Group	30	0.76	0.83	5.4*	58
Control Group	30	2.36	1.66		

* significant at the level of 0.05 level.

To find out if there is any difference between the mean post test level of oral mucositis score between the experimental group and control group, the null hypothesis was stated as follows

H02: The mean post test level of oral mucositis score in experimental group of patients with cancer receiving chemotherapy will not be significantly lesser than the mean post test score of patients with cancer receiving chemotherapy in control group.

Table 11 shows that the mean post test score of oral mucositis in experimental group (0.76) was lesser than the mean post test score of control group(2.36). The obtained 't' value 5.4 of df 58 is significant at 0.05 level. This difference between the mean(1.16), is a true difference and has not occurred by chance. So, it can be inferred that application of flavored ice cubes has a significant role in improving the mucositis status. So, the researcher rejects the null hypothesis and accepts the research hypothesis.

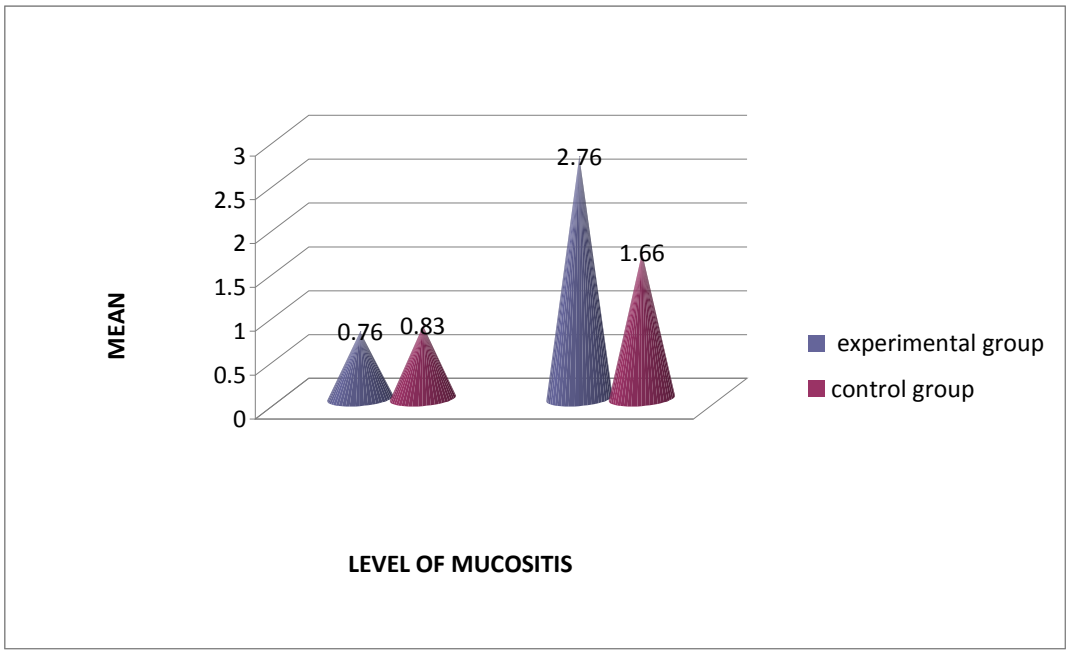


FIG 18 : Comparison of mean post test level of oral mucositis of the experimental group and control group on day 21

SECTION – 4

Table 12: Association between the levels of mucositis of experimental and control group before the use of flavored ICE cubes with demographic variables

Variables	Above Mean	Below Mean	$\chi 2$	Df
Age: (in years)				
➢ 20 – 30 years	1	3		
➢ 31 – 40 years	8	4		
➢ 41 – 50 years	5	6	4.186#	4
➢ 51 – 60 years	12	9		
➢ 61 – 70 years	4	8		
Sex:				
➢ Male	18	19	0.070#	1
➢ Female	12	11		
Education:				
➢ Primary	8	7	1.91#	3
➢ Secondary	11	6		
➢ Higher Secondary	2	4		
➢ Illiterate	11	11		
Occupation:				
➢ Employed	23	19	1.270#	1
➢ Unemployed	7	11		
Type of Cancer:				
➢ Lung Cancer	7	10		
➢ Stomach Cancer	5	5		
➢ Cervical Cancer	7	7		
➢ Colon Cancer	8	0		
➢ Rectal Cancer	1	2	7.3#	11
➢ Overian Cancer	1	3		
➢ Cricoid Cancer	2	0		

Table cont…

Variables	Above Mean	Below Mean	$\chi 2$	Df
➢ Hodgkins Lymphoma	1	1		
➢ Cancer Skin	1			
➢ Ca nasopharynx	1	0		
➢ Ca Supraglottis	0	1		
➢ Ca larynx	1	1		
Habits of tobacco chewing:				
➢ Yes	2	2	8.722*	1
➢ No	27	29		
Habit of betel nut chewing:				
➢ Yes	2	1	0.42#	1
➢ No	27	30		
Habit of Smoking:				
➢ Yes	11	13	0.27#	1
➢ No	19	17		
Habit of Kutka:				
➢ Yes	0	0	0#	1
➢ No	0	0		
Habit of Pan:				
➢ Yes	2	1	0.38#	1
➢ No	27	30		
Drugs used:				
➢ Cisplatin + 5FU	7	17		
➢ Cisplatin + etoposide	16	6	8.712*	2
➢ Others*	7	7		

* Significant at 0.05 level # not significant at 0.05 level.

To find out if there is any association between oral mucositis score of subjects and the selected demographic variables of age, sex, education, occupation, habits of pan masala, tobacco, betel nut, kutka chewing, smoking, type of cancer, chemodrugs used

H03: There will be no significant association between the pre test level of oral mucositis score and demographic variables of age, sex, education, occupation, habits of pan masala, tobacco, betel nut, kutka chewing, smoking, type of cancer, chemodrugs used. .

Inorder to find out the association between the oral mucositis score and selected demographic variables chi square test was computed.

Regarding the association between the mucositis score and Age, the obtained chi-square value of 4.186 at df 4 (9.49)was not significant at p(<0.05)level.

Regarding mucositis score and sex the chi-square value of 0.70 at df (1)p(<0.05) shows no significance.

Regarding mucositis score and education the chi square value of 1.946 at df3 (7.82) p(<0.05) shows no significance

Regarding mucositis score and occupation the chi-square value of 1.270 at df1 (3.84) p(<0.05) shows no significance.

Regarding mucositis score and type of cancer the chisquare value of 7.3 at df 11 (19.68) p(<0.05) shows no significance

Regarding mucositis score and habits of betel nut, kutka, panmasala chewing and smoking the chisquare value of 0.42, 0.27, and o.351 at df 1 (3.84) p(<0.05) shows no significance

Regarding the association between the oral mucositis score and habit of tobacco chewing the chi-square value of 8.722 at df (1) P (>0.05) shows significance.

Regarding the association between the usage of drugs and oral mucositis the chi square value shows significance of 8. 712 at df (2) at level of 0.05.

With regard to these demographic variables of tobacco chewing and chemo drugs used significant association is seen, between the pre test level of oral mucositis score, hence the research hypothesis is accepted.

CHAPTER - V

DISCUSSION

Oral mucositis (OM) is a common symptom effect of radiation and chemotherapy. It is defined as an inflammation of oral mucosa resulting from cancer therapy typically manifesting as atrophy, swelling, erythema and ulceration (Sonis, 2004).

It has a serious impact on those who are undergoing cancer treatment. It will affect treatment schedule by delay or discontinued treatment, quality of life and aspects of daily living (Brown, 2010).

However, prevention and management of OM are challenging issues for health care professionals. Unfortunately, we are still unable to offer curative solutions to those patients who suffer from OM.

Numerous methods have been tested to cope with this problem. This study was conducted to evaluate the effectiveness of flavored ice cubes in oral mucositis among patients with cancer receiving chemotherapy at Devaki Cancer and Research Centre, Madurai .

The study consisted total of 60 samples, 30 in the experimental group and 30 in the control group. The design adopted for this study was pre-test post-test true experimental control group design. The tool used for study was oral mucositis assessment scale.

The study findings are discussed in this chapter with reference to the objectives and hypotheses as stated in chapter –I for the discussion to be effective some of the objectives are clubbed together.

DISTRIBUTION OF SAMPLES WITH REGARD TO DEMOGRAPHIC AND CLINICAL CHARACTERISTICS:

The samples of the study included both males and females, in this study the number of males with cancer was high in both the groups (experimental-. 21(70%) and 16(53.33%) in control group).

Majority of samples were between 51-60 years with, 11(36.67%)-in experimental group and 10(33.33%) in control group. Most of the samples in experimental group have undergone primary education (30%) and in control group most of the samples underwent secondary education (36.66%). With regard to occupation both in experimental group and control group the majority of the samples were employed with 20(66.66%) and 22(73.33%) respectively. Both in experimental group and control group majority of the samples were having lung cancer(26.66%) and (30%), stomach cancer 5(16.66%) and 5 (16.66%), cervical cancer 7(23.33%) and 8(26.67%) . smoking is the major habit seen in the groups in 1/3rd (40%) in total than the other habits of beetel nut chewing, tobacco chewing, Kutka and Pan Masala chewing. 13% of samples had habit of smoking in experimental group and 11% in control group.

THE FIRST OBJECTIVE OF THE STUDY IS TO DETERMINE THE LEVEL OF MUCOSITIS IN PATIENTS WITH CANCER RECEIVING CHEMOTHERAPY IN EXPERIMENTAL GROUPS BEFORE AND AFTER USING FLAVORED ICE CUBES.

In this study, on day 1 pre test among the experimental group, 70% had mild ulceration and 86.66% had not severe erythema. On post test day 3, the 50% had mild ulceration and 70% had no erythema. On post test day 21, 73.33% had no ulceration and 60% had no erythema. Heydari, Sharifi, Salek, (2012), described that, symptomatic relief from mouth pain can be

achieved by sucking ice chips when the chemotherapy drug is most concentrated in the body. This technique, called cryotherapy, works by decreasing blood flow to sores.

Baydar, Dilkitas, Sevine, Senel, and Aydogdu, (2005), studied the effects of local cryotherapy on mucositis incidence administrated during 5-FU treatment. Among a total of 99 courses, 5-FU and folinic acid combination chemotherapy was given to 40 patients. Cryotherapy was given to the same patient in one course but not given in the next. Findings revealed that While mucositis developed in 6.7% of the courses given with cryotherapy, this ratio was 38.9% in courses given without cryotherapy. In the logistic regression analysis, development of mucositis had been found to correlate only with cryotherapy. Odds ratio (OR) = 11.5; in the 95% confidence interval (CI) = 3.2 - 41.9; (p = 0.001). They concluded that oral cooling prevents 5-FU induced mucositis. This effective prophylactic treatment should be used in patients who are at increased risk for developing 5-FU induced mucositis.

THE SECOND OBJECTIVE IS TO DETERMINE THE PRE TEST AND POST TEST LEVEL OF ORAL MUCOSITIS AMONG PATIENTS WITH CANCER RECEIVING CHEMOTHERAPY IN CONTROL GROUP

In control group, 73.33% had mild ulceration and 60% had not severe erythema.on post test day 3 90% had mild ulceration and 96.6% had not severe erythema.on day 21 70% had mild ulceration and 93.33% had not severe erythema.

Herlofson, Norman-Pedersen , Redfors , Fosså , (1997), studied that cancer chemotherapy often leads to injury of normal cells. Adverse effects on oral mucosa have been documented for several cytotoxic treatment regimens. They conducted a retrospective study among 39 patients undergoing cisplatin based chemotherapy regimen. The patients were divided into two groups, a case group (24 individuals) having received 4 7 cycles of cisplatin-based

chemotherapy in addition to surgery, and a control group (15 individuals) treated with surgery alone. The study revealed that 62% of the patients in the chemotherapy group developed adverse soft tissue reactions, with mucositis and pain as chief complaints, whereas none in the control group experienced any mucosal complications.

According to Bio Medical Centre of Oral Health, (2006)., Oral mucositis (OM) is multifactorial in nature. The disruption or loss of rapidly dividing epithelial progenitor cells is a trigger for the onset of the disorder. However, the actual manifest dysfunction and its severity and duration are greatly influenced by changes in other cell populations, immune responses and the effects of oral flora. This toxicity frequently complicates the course of autologous bone marrow transplantation; it causes severe pain as well as cramping, nausea and gastro-enteritis. In addition, food and fluid intake may be poor, the ability to absorb nutrients much reduced and the susceptibility to infection greatly increased. The nature and degree of mucositis experienced by a patient varies according to the treatment regimen applied (combination of radiotherapy and chemotherapy, dosage, duration and sequence). Mucositis can therefore result in under-nutrition and significantly decreases a patient's quality of life. Modulation of the treatment regimen (use of lower doses or long recovery intervals between doses) remains the most effective means of limiting the actual incidence and severity. This event can therefore compromise patient prognosis.

THE THIRD OBJECTIVE IS TO CHECK THE EFFECTIVENESS OF FLAVORED ICE CUBES ON MUCOSITIS AMONG PATIENTS WITH CANCER RECEIVING CHEMOTHERPAY

As per the table 9 shows that the mean post test score of oral mucositis in experimental group on day 3 was 1.13 which was lower than the mean post test score (3.8) of control group.

The obtained ‘t’ value of 8.6 was significant at 0.05 level. As per the data on table 10, the mean post test score of oral mucositis in experimental group on day 21 was 0.76 which was lower than the mean post test score (2.50) of control group on day 21. The obtained ‘t’ value of 0.58 is not significant at the level of 0.05. The difference in the mean could be due to the effect of oral cryotherpay.

Cascinu, Fedeli, catalano, (1994)conducted a randomised study that demonstrated the utility of oral cooling (cryotherapy) in the prevention of 5-fluorouracil (5FU)-induced stomatitis. In order to verify these results a confirmatory study, using identical treatment regimen, was initiated. 84 patients treated with a 5-FU-containing regimen were randomised to a control arm or to receive oral cryotherapy. End point evaluation was obtained by a global assessment of the physician's judgement and patients' description of mucositis severity graded 0–4. Mucositis was significantly reduced by cryotherapy considering both the first cycle of therapy (the mean toxicity score for cryotherapy was 0.59 and it was 1.1 for the control group, $P>0.05$) and all the chemotherapeutic courses (the mean toxicity score for cryotherapy was 0.36 when it was 0.69 for the control group, $P>0.05$). In conclusion, the present study confirms that cryotherapy can decrease 5FU-induced stomatitis and should be recommended for patients receiving bolus 5FU-containing regimens.

RajeshLalla (2008)., it has been hypothesized that topical administration of ice chips to the oral cavity during administration of chemotherapy results in decreased delivery of the chemotherapeutic agent to the oral mucosa. This effect is presumably mediated through local vasoconstriction and reduced blood flow. Several studies have demonstrated that cryotherapy reduces the severity of oral mucositis in patients receiving bolus doses of chemotherapeutic agents.

THE FOURTH OBJECTIVE IS TO FIND OUT THE ASSOCIATION BETWEEN THE PRETEST LEVELS OF MUCOSA AMONG PATIENTS WITH CANCER WITH SELECTED DEMOGRAPHIC VARIABLES.

The study findings shows there is significant association between the oral mucositis and habit of tobacco chewing. The chi square value of 8.722 at df 1 p(>0.05) shows significance and the association between the level of oral mucositis and the treatment regimen followed the chi square valueof df 2 (8.712) shows significance at p(>0.05).

According to oralcancerfoundtation.org, Oral mucositis is probably the most common, debilitating complication of cancer treatments, particularly chemotherapy and radiation. It can lead to several problems, including pain, nutritional problems as a result of inability to eat, and increased risk of infection due to open sores in the mucosa. It has a significant effect on the patient's quality of life and can be dose-limiting (i.e., requiring a reduction in subsequent chemotherapy doses).Factor that can increase the likelihood of developing mucositis, or that can make it worse if it does occur, include habit of tobacco chewing.

CHAPTER - VI

SUMMARY, CONCLUSION, IMPLICATIONS AND RECOMMENDATIONS

According to Daniela Alterio et al (2007)The topical application of ice chips (cryotherapy) on the inflamed mucosa is based on the hypothesis that temporary local vasoconstriction of the oral mucosa vessels could reduce exposure of the replicating epithelium cells to peak levels of some cytostatic agents.

This chapter presents the summary, major findings, conclusion, implications and recommendations of the study.

SUMMARY

The aim of the study was to determine the effectiveness of oral cryotherapy in oral mucositis among patients with cancer receiving chemotherapy.

The objectives of the study.

- To determine the level of oral mucositis among patients with cancer receiving chemotherapy in experimental group before and after using flavored ice cubes.
- To determine the pre and post test level of oral mucositis among patients with cancer receiving chemotherapy in control group.
- To check the effectiveness of flavored ice cubes on oral mucositis among patients with cancer receiving chemotherapy.
- To find out the association between the pre test level of oral mucositis among patients receiving chemotherpay and selected demographic variable.

The following hypotheses were set for the study, and all hypotheses were tested at 0.05 level of significance

- The mean post-test level of mucositis score among patients with cancer receiving chemotherapy will be significantly lower than their mean pre-test level of mucositis score in experimental group.
- The mean post test level of mucositis score in experimental group of patients with cancer receiving chemotherapy will be significantly lesser than the mean post test score of patients with cancer receiving chemotherapy in control group.
- There will be significant association between the pre test level of mucositis and demographic variables(age, sex, occupation, education, occupation, habits of smoking, tobacco chewing, Kutka and Panmasala chewing, type of cancer, chemo drugs used)

MAJOR FINDINGS OF THE STUDY

Demographic characteristics of the Samples

- With regard to age, both in experimental group and control group majority of samples were between 51-60 years ,11(36.67%) and 10(33.33%) respectively.
- Regarding sex, in both experimental group and control group the majority of the samples were males. 21(70%) and 16(53.33%) respectively.
- With regard to education both in experimental group and control group the majority of the samples were illiterate 10(33.33%) and 12 (40%) respectively.
- Wit regard to occupation both in experimental group and control group the majority of the samples were employed 20(66.66%) and 22(73.33%) respectively.

- Regarding the type of cancer both in experimental group and control group majority of the samples were having lung cancer (26.66%) and (30%), stomach cancer 5(16.66%) and 5 (16.66%), cervical cancer 7(23.33%) and 8(26.67%) respectively.
- Regarding the habit of tobacco chewing, majority of the samples in experimental group and control group had no habit of tobacco chewing 27(90%) and 29(96.6%) respectively.
- With regard to habit of betel nut chewing both in experimental group and control group majority of the samples had no habit of betel nut chewing 28(93.33%) and 29(96.6%) respectively.
- Regarding the habit of smoking majority of the samples in experimental group and control group had no habit of smoking 17(56.66%) and 19(63.33%) respectively.
- With regard to habit of kutka usage majority of the samples in experimental and control group shows no usage 30(100%) and 30(100%) respectively.
- Regarding the habit of pan chewing both in experimental group and control group majority of the samples had no habit of pan chewing 28(93.33%) and 29(96.66%) respectively.
- In regard to drug usage of the samples in experimental group cisplatin + 5FU was used in 23.3% of samples, cisplatin + Etoposide was used in 53.3% of the samples. Other drugs like cisplatin + Paclitaxel, cisplatin + irinotecan, cisplatin + gemcitabine, was used 23.3% of samples. In control group cisplatin + 5FU was used in 56.7% of samples. Cisplatin + etoposide was used in 20% of samples. Other drugs was used in 23.3% of samples.

In experimental group, 21(70%) had mild ulceration and 26(86.66%) had not severe erythema before the application of flavored ice cubes, whereas after the application of flavored

ice on 3rd day the subjects 15(50%) had no ulceration and 15(50%) had mild ulceration and 21(70%)had no erythema and 9(30)had not severe erythema and on 21st day 22(73.33%) had no ulcer and 18(60%) had no erythema.

In control group 22(73.3%) had mild ulceration and 18 (60%) had not severe erythema on pre-test whereas on 3rd post test day 27(90%) had mild ulceration and 29(96.66%) had not severe erythema and on 21st day 21(70%)had mild ulceration and 28(93.33%)had not severe erythema.

In experimental group on 3rdday the subjects 15(50%) had no ulcer and 15(50%) had mild ulcer and 21(70%) had no erythema and 9(30%) had not severe erythema . In control group on 3rd day the subjects 3(10%)had no ulcer and 27(90%)had mild ulcer and 1(3.33%)had no erythema and 29(96.67%)had not severe erythema .

In experimental group and control group on 21st day the subjects 22(73.33%) had no ulcer and 8(26.66%)had mild ulcer and 18(60%)had no erythema and 12(40%) had no erythema. In control group the subjects 9(30%)had no ulcer and 21(70%) had mild ulcer and 2(6.67%)had no erythema and 28(93.33%)had not severe erythema.

Mean post test level of mucositis (1.13) after the application of flavored ice .cubes was lower than the mean pretest level of mucositis (2.76) before the use of ice cubes. The obtained t value is greater than the table value. This indicates that the application of ice cubes in oral mucositis is effective in reducing the oral mucositis.

Mean post test level of mucositis (0.76) after the application of flavored ice .cubes was lower than the mean pretest level of mucositis (2.76) before the use of ice cubes. The obtained t value is greater than the table value. This indicates that the application of ice cubes in oral mucositis is effective in reducing the oral mucositis.

Mean post test level of mucositis in experimental group (1.13) after the application of flavored ice cubes was lower than the mean post test level of mucositis in control group (3.8). The obtained t value is greater than the table value. This indicates that the application of ice cubes in oral mucositis is effective in reducing the oral mucositis

Mean post test level of mucositis in experimental group (0.76) after the application of flavored ice cubes was lower than the mean post test level of mucositis in control group (2.50). The obtained t value is lesser than the table value. This indicates that the application of ice cubes in oral mucositis is not effective in reducing the oral mucositis.

There was a significant association between, chemodrug usage and severity of oralmucositis in cancer patients receiving chemotherapy.

There was significant association between the level of oralmucositis and selected demographic variable – tobacco chewing.

CONCLUSIONS

The following conclusions were drawn from the study

- Patients with cancer undergoing chemotherapy showed significant decrease in the level of mucositis after receiving application of flavored ice cubes..
- The level of oral mucositis among patients with cancer on chemotherapy in experimental group shows significant decrease (0.76) after the application of flavored ice cubes than the pre test score (2.76), shows the effectiveness of application of flavored ice cubes.
- The post test level of oral mucositis (2.36) was lower than the pre test score (2.63) of oral mucositis in the control group.

- The study finding says that there is significant association between level of oral mucositis and habit of tobacco chewing. $\chi 2$ 8.722 p(>0.05) and the chemo drugs used $\chi 2$ (8.712) p(>0.05).

IMPLICATIONS

This study has many implications in the field of nursing this includes nursing practice, nursing education, nursing research and nursing administration.

NURSING PRACTICE

- The findings of the study ensure that application of ice cubes for patients with cancer receiving chemotherapy reduces and prevents the damage of the oral mucosa.
- Cryotherapy reduces the amount of drug reaching the oral mucous membrane and may therefore reduce the mucositis caused by the cytotoxic effects of the drugs.
- A standard approach can be followed which includes a baseline of assessment consisting of risk assessment and oral inspection before any patients commences chemotherapy..
- This evidence based practice will enhance quality and standards of nursing care given to the patient in the management of oral mucositis.
- Routine practice of this ice cube application prevents patient from getting acquired to infection and malnourishment, and improves the treatment compliance and quality of life of patients.
- Cryotherapy is a simple, easy, well tolerated, non-expensive and safe method with limited side effects. It improves nursing performance and practice from symptom relief to symptom prevention of oral mucositis.

NURSING EDUCATION

- Conducting Conferences for the staff nurses with a focus on the best evidence on prevention and treatment of oral mucositis to increase the awareness and to reduce dilemmas in the best method of prevention and treatment.
- Conducting an awareness campaign about the risk factors associated with mucositis will allow nurses to identify cancer patients at greater risk and incorporate supportive care measures into their management plans

NURSING RESEARCH

- Research shall be done on the concept of effectiveness of oral cooling by the usage of cold water swishing, ice chips swishing in the reduction of oral mucositis.
- Findings of the study will provide the base line data about the oral mucositis healing and it can be used for further studies in this area.
- Investigating this intervention in other chemotherapy regimens with large sample size helps to generalise the findings.
- Clinical trials shall be done in patients undergoing chemotherapy with few other drugs.

NURSING ADMINISTRATION

- Nurse administrators should prepare protocols for the effective usage of oral cryotherapy to practice in routine among the cancer patients receiving chemotherapy in clinical settings.
- Nurse administrators shall enhance researchers to do clinicaltrials to broaden the potential applications of cryotherapy in clinical settings.

LIMITATIONS

The study was done on small sample size of 60, hence generalizations is possible only for the selected populations in Devaki Cancer and Research Institue, Madurai during the data collection period.

RECOMMENDATIONS

- The study can be concluded using large populations to generalize the findings.
- A longitudinal study can be conducted to assess the effectiveness of selected nursing intervention on reducing the chemotherapy induced oral mucositis.
- Various techniques like ice chip and cold water swishing can be tried among similar samples
- Randomized clinical trial cross over study shall be done to prove the effectiveness of oral cryotherapy using plain and flavored ice cubes in the reduction of oral mucositis.
- Qualitative study can be conducted to study the effects of oral mucositis in the quality of life of patients undergoing chemotherapy.
- Incidence of oral mucositis and its risk shall be assessed among cancer patients receiving chemotherapy.

REFERENCES

- Alterio D, Jereczek-Fossa BA, Zuccotti GF, Leon ME, Omodeo Sale E, Pasetti M, Modena T, Perugini P, Mariani L and Orecchia R. (2006). Tetracaine oral gel in patients treated with radiotherapy for head and neck cancer: final results of a phase II study. *Int J Radiat Oncol Biol Phys* 64(2): 392-395.
- Baydar M, Dikilitas M, Sevine A, Senel S, Senel F and Aydogdu I. (2005) .Prevention of oral mucositis due to 5-fluorouracil treatment with oral cryotherapy. *J Natl Med Assoc* 97(8):1161-1164
- Brown, C. (2010). *Cancer Nursing principles and practice*.7th ed. http://www.hsag.co.za/index.php/HSAG/article/view/632/751
- Cascinu S, Fedeli A, Fedeli SL and Catalano G. (1994). Oral cooling (cryotherapy), an effective treatment for the prevention of 5- fluorouracil-induced stomatitis. *Eur J Cancer B Oral Oncol* 30B(4): 234-236.
- CastellinoFlavia. (july, 2011). Effectiveness of plain vs flavored icecubes in preventing oral mucositis associated with injection 5-FU among cancer patients. *International Journal of Nursing Education. Volume* : 3(2). Retrieved from http://www.indianjournals.com /ijor.aspx?target=ijor:ijone& volume=3&issue=2&article=012
- Chintamani.lewis . (2011). *Text Book of Medical surgical nursing. Assessment and Management Of clinical problems*. elsevier publications.pno: 218, 278.

- D. E. Peterson. Management of oral and gastrointestinal mucositis. *ESMO Clinical Practice Guidelines.* Department of Oral Health and Diagnostic Sciences, School of Dental Medicine, Program in Head & Neck Cancer and Oral Oncology Program, Neag Comprehensive Cancer Center, University of Connecticut Health Center, Farmington, Connecticut, USA.
- Denise F. Polit, Cheryl, Totano Beck. (2012). *Nursing Research Generating and Assessing Evidence for Nursing Practice.* IXth edition. Lippincott William & Wilkins Publications. P.No:723, 727.
- Djuric M, Hillier-Kolarov V, Belic A and Jankovic L . (2006). Mucositis prevention by improved dental care in acute leukemia patients. *Support Care Cancer, 14(2)*: 137-146. Retrieved from ar.liarjournals.org/content/27/2/1105.full.pdf.
- Douherty, L. & Bailey, C. (2008). Chemotherapy. in J. Corner & C. Bailey, (eds.). *Cancer nursing: Care in context,* pp. 267–316, Blackwell, Oxford.
- Eilers, J. (2004). Nursing interventions and supportive care for the prevention and treatment of oral mucositis associated with cancer treatment. *Oncology Nursing Forum*, 31(Suppl. 4), 13-23. http://www.ons.org/Research/PEP.
- Evans D.(2008). More than a sore mouth: patients' experience of oral mucositis. *Oncol Nurs Forum.* 29(7):1051-7. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/12183754
- Fred Hutchinson Cancer Research Center, the Seattle Cancer Care Alliance and the University of Washington, Seattle, WA, USA

- Heydari, A., Sharifi, H., & Salek, R. (2012). Effect of Oral Cryotherapy on Combination Chemotherapy-induced Oral Mucositis: A Randomized Clinical Trial. *Middle East Journal of Cancer*, 3(2 & 3) http://cancer.unm.edu/cancer/cancer-info/cancer-treatment/side-effects-of-cancer-treatment/common-side-effects/mouth-sore
- Herlofson BB, Norman-Peterson K, Redfors M, Fossa SD. (1997). Oral mucosal side effects of cyto toxic chemotherapy of testicular cancer. A retrospective study. Eur J oral Sci, 105(2), 523-6. *Retrieved from www.ncbi.nlm.nih.gov/pubmed/9395118*
- International Agency for Research on Cancer. American cancer soceity. (2011*). Global cancer facts and figures. Second edition.* Pno. 1. Retrieved from www.cancer.org/acs/groups/content/@epidemiologysurveillance/documents/acspc-027766.pdf.
- James' D Olimpio. (2008). *Oral mucositis – causative regimens and pathways for treatment.* McMahon publishing, newyork. P. no: 19 retrieved from http://www.clinicaloncology.com/download/pg08114_mucositis_WM.pdf
- Karagozoglu S and Filiz Ulusoy M.(2005).Chemotherapy: the effect of oral cryotherapy on the development of mucositis. *J ClinNurs* 14(6): 754-765.
- Lilleby K, Garcia P, Gooley T. (2006). A prospective, randomized study of cryotherapy during administration of high-dose melphalan to decrease the severity and duration of oral mucositis in patients with multiple myeloma undergoing autologous peripheral blood stem cell transplantation. *Bone*

Marrow Transplantation.;1031-1035http://news.cancerconnect.com/ice-chips-prevent-mouth-sores-associated-with-high-dose-chemotherapy/

- Maddyreddy Umamaheshwar Rao Naidu, Gogula Venkat Ramana, Pingali Usharani, Iyyappa Krishna Mohan, Avula saman, Priyadharshini Roy. (2004). *Chemotherapy induced and or Radiation therapy induced oral mucositis complicating the treatment of cancer*. 6(5).pno. 423 – 431. Retrieved from ncbi.nlm.nih.gov/articles/pmc1531648.
- Mahood DJ, Dose AM, Loprinzi CL. (March, 1991). Inhibition of 5-fluorouracil-induced stomatitis by oral cryotherapy. *J Clin Oncol*. 9(3):449–452.
- *Managing oral mucositis*. (2011).connect book series. Retrieved from media.cancercare.org/publications/original/133ccc_oral_mucositis.pdf/1321542632.
- Migliorati CA, Oberle-Edwards L, Schubert M. (2006 Jun). The role of alternative and natural agents, cryotherapy, and/or laser for management of alimentary mucositis. *Support Care Cancer*. 14(6):533–540. [PubMed]
- *Mouth sores caused by cancer treatment*. How to cope, understand, how to manage cancer treatment side effests, including mouth sores, so that you can feel more in control as you go through cancer treatment.(2011). Retrieved from. mayoclinic.org/disease+condition/cancer/indepth/mouth sores/art-20045486.
- Naidu MU, Ramana GV, Ratnam SV, Sudhavani T, Naidu KJ, Roy P, Suresh P, Rani PU and Mohan IK.(2005). A randomized double-blind, parallel,

placebo-controlled study to evaluate the efficacy of MF5232 (Mucotrol), a concentrated oral gel wafer, in the treatment of oral mucositis. Drugs R D 6(5): 291-298.http://emedicine.medscape.com/article/1079570-12

- Newton, S., Hickey, M. & Marrs, J. (2009). *Mosby's oncology nursing advisor*, St Louis, Mosby. Retrieved from http://www.hsag.co.za/index.php/HSAG/article/viewFile/632/750
- Nikoletti S, Hyde S, Shaw T, Myers H, Kristjanson L. (2005).**Comparison of plain ice and flavoured ice for preventing oral mucositis associated with the use of 5-fluorouracil.** *J Clin Nurs*.14:750–753
- Peterson DE. Oral mucositis. (2005 Jan) *Dent Clin North Am* 49(1):167–184. [PubMed]
- Poon, Sze-wan.(2012). *An evidence-based guideline on using cryotherapy for chemotherapy-induced oral mucositis in adult cancer patients*. Retrieved on 2013-08-07 from http://oatd.org/ oatd/record? record=oai\:hub.hku.hk\: 10722\%2F174285
- Poon, Sze-wan.(2012). *An evidence-based guideline on using cryotherapy for chemotherapy-induced oral mucositis in adult cancer patients*. Retrieved on 2013-08-07 from http://oatd.org/oatd/record? record=oai\:hub.hku.hk\: 10722\%2F174285
- R. Sankaranarayanan and P. Boffetta. (2010). Research on cancer prevention, detection and management in low- and medium-income countries. *Annals of Oncology*.21(10). Retrieved from http://annonc.oxfordjournals.org/ content/21/10/1935.full

- Rajesh. V.lalla, Stephen. T Sonis, Douglas E. Peterson. (2008). Management of oral mucositis in patients with cancer. *Dent Clin North AM.*52(1).PMCID 2266835; Retrieved from www.ncbi.nlm.nih.gov/pmc/articles/pmc2266835.
- Richard, David, Faragher. (1997*). Biology of cancer. Oncology* Nursing secrets. Jaypee publications. Pno.1.
- Rubenstein, EB., Peterson, DE., Schubert, M. (2004). *Clinical practice guideline for the prevention and treatment of cancer therapy-induced oral and gastrointestinal mucositis.* Cancer.100:2026-2046
- Saba Bashtawi RN. (December, 2013). cryotherapy effects in prevention of oral mucositis in adult patients who received chemotherapy. an evidence based review. *Middle east journal of nursing, 7 (6).*
- Scully C, Epstein J and Sonis S. (2003) .Oral mucositis: a challenging complication of radiotherapy, chemotherapy, and radio-chemotherapy. Part 1: *pathogenesis and prophylaxis of mucositis*. Head Neck *25(12)*: 1057-1070.
- Sonis ST, Elting LS, Keefe D. (2004). Perspectives on Cancer Therapy-Induced Mucosal Injury: Pathogenesis, Measurement, Epidemiology, and Consequences for Patients. Cancer. 100(S9):1995–2025. [PubMed]
- Sonis, S., (2007). Pathobiology of oral mucositis: novel insights and opportunities. *Journal of Supportive Oncology* 9, 3–11.
- Susan K. Grove and Nancy Burns. (2006). *Understanding Nursing Research Evidenced Based Practice.* Fourth Edition. P.No:43.
- Suresh. K. Sharma. (2010). *Nursing Research & Statistics.* Elser Publications.

- Svanberg, A., Ohrn, K., & Birgegard, G.(2007). Oral cryotherapy reduces mucositis and opioid use after myeloablative therapy-a randomized controlled trial. *Journal of Clinical Nursing*
- Witt, M. (2007). *'Mucositis'*, in M. Haas, W. Hogle, G. Moore-Higgs, T. Gosselin-Acomb, (eds.). *Radiation Therapy. A guide to patient care*, pp. 563–573, Mosby, St Louis

RELATED WEBSITES:

- www.cancer.org/acs/groups/content/@epidemiologysurveillance/documents/acspc-027766.pdf.
- www.mayoclinic.org/disease+condition/cancer/indepth/mouth sores/art-20045486
- www.ncbi.nlm.nih.gov/articles/pmc1531648
- www.ar.liarjournals.org/content/27/2/1105.full.pdf.
- www.ncbi.nlm.nih.gov/pmc/articles/pmc2266835.
- www.media.cancercare.org/publications/original/133-ccc_oral_mucositis.pdf/1321542632.
- http://www.indianjournals.com/ijor.aspx?target=ijor:ijone&volume=3&issue=2&article=01
- http://oatd.org/oatd/record?record=oai\:hub.hku.hk\:10722\%2F174285
- http://www.nvydiamedical.com/products/mucofate/prevalence-of-oral-mucositis/
- http://www.hsag.co.za/index.php/HSAG/article/viewFile/632/750
- http://oatd.org/oatd/record?record=oai\:hub.hku.hk\:10722\%2F174285
- www.ncbi.nlm.nih.gov/pubmed/12183754
- www.ncbi.nlm.nih.gov/pubmed/12183754
- http://annonc.oxfordjournals.org/content/21/10/1935.full
- http://emedicine.medscape.com/article/1079570
- http://www.clinicaloncology.com/download/pg08114_mucositis_WM.pdf
- http://news.cancerconnect.com/ice-chips-prevent-mouth-sores-associated-with-high-dose-chemotherapy/
- www.oralcancerfoundation.org/treatment/mucositis.html.(2012)
- http://www.hsag.co.za/index.php/HSAG/article/view/632/751

- http://www.ncbi.nlm.nih.gov/pubmed/?term=Lalla%20RV%5Bauth%5D
- http://www.ons.org/Research/PEP.
- http://www.biomedcentral.com/1472-6831/6/13
- http://www.ons.org/Research/PEP.
- http://cancer.unm.edu/cancer/cancer-info/cancer-treatment/side-effects-of-cancer-treatment/common-side-effects/mouth-sore
- www.lwwoncology.com

APPENDIX – I

SACRED HEART NURSING COLLEGE

ULTRA TRUST

4/235, COLLEGE ROAD,
THASILDAR NAGAR,
MADURAI - 625 020. TAMILNADU, INDIA
PHONE : 0452 - 2534593
Email : ultratrust@rediffmail.com

Ref: UT: SHNC: 2013

Date: 12.06.2013

To

The Medical Director
Devaki Cancer Institute
Madurai

Sub: Sacred Heart Nursing College, Madurai – Project work of M.Sc., (N) Student - Permission - regarding.

Respected Sir / Madam,

We wish to state that **Ms. ANANDHA PARKAVI. C,** final year M.Sc., (N) student of Sacred Heart Nursing College has to conduct a research Project, which is to be submitted to the Tamil Nadu Dr. M.G.R. Medical University, Chennai in partial fulfillment of University requirements.

The Topic of research project is "*Evaluating the effectiveness of flavored ice cubes on oral mucositis among patients with cancer receiving chemotherapy*".

We therefore request you to kindly permit her to do the research work in your area.

Thanking you,

Yours faithfully

PRINCIPAL
SACRED HEART NURSING COLLEGE
ULTRA TRUST, MADURAI

APPENDIX – II

CONTENT VALIDITY CERTIFICATE

This is to certify that I Mrs. S. CHANDRAKALA have gone through the tool submitted by Ms.C.Anandha parkavi doing her research as a fulfillment of master of science in nursing under the Tamilnadu Dr.M.G.R Medical University, Chennai.

The statement of the problem in her study is " **An experimental study to evaluate the effectiveness of flavored ice cubes on oral mucositis of patients with cancer receiving chemotherapy"**

I have gone through the tool for construct, content and criterion validity. I certify that this tool can be used for above mentioned study.

29/6/13

Signature, Designation & seal of the expert

Prof. S. CHANDRAKALA, MSc (N)
VICE PRINCIPAL, HOD OF MED. SUR.DEPT.,
SACRED HEART NURSING COLLEGE
ULTRA TRUST, MADURAI-20

APPENDIX - III

LIST OF EXPERTS

1. Dr. Rajaram, M.D.,
   Medical Oncologist,
   Devaki Cancer & Research Institute, Madurai.
2. Dr. Krishna Kumar, MD,
   Medical Oncologist, Meenakshi Mission, Madurai.
3. Prof.Mrs. Chandrakala, M.Sc (N), Ph.D.,
   Vice Principal,
   Sacred Heart Nursing College, Madurai
4. Mrs. Devakirubai, M. Sc (N), Ph. D.,
   Professor, Sacred Heart Nursing College,
   Madurai.
5. Mrs. Manjula, M.Sc (N), Ph.D.,
   Professor, Sacred Heart Nursing College,
   Madurai.
6. Mrs. Andal, M.Sc (N), Ph.D.,
   Asst. Professor,
   Sacred Heart Nursing College,
   Madurai.
7. Mr. Vijayakumar,
   Bio-Statistician,
   Aravindh Eye Hospital, Madurai.

APPENDIX – IV

TOOL TO ASSESS THE LEVEL OF ORAL MUCOSITIS

SECTION - I

DEMOGRAPHIC DATA

SAMPLE NO:

1. Age
2. Sex
3. Education
4. Occupation
5. Habit of
    - Panmasala chewing:

      Yes/no
    - Tobacco chewing:

      Yes/no
    - Smoking:

      Yes/no
    - Betel nut chewing:

      Yes/no
    - Kutka chewing:

      yes/no:

SECTION - II

CLINICAL PROFILE:

1. Type of cancer:
2. Chemo drugs used:

SECTION – III

ORAL MUCOSITIS ASSESSMENT SCALE

Location	Ulceration Cm^2	Score	Pre Test	Post test day 3	Post test day 3	Erythema	Score	Pre test day 1	Post test Day 3	Post test day 21
Lip lower	none <1cm 1-3cm 3cm	0 1 2 3				none not severe severe	0 1 2			
upper	none <1cm 1-3cm 3cm	0 1 2 3				none not severe severe	0			
Buccal mucosa Right	none <1cm 1-3cm 3cm	0 1 2 3				none not severe severe	1			
Left	none <1cm 1-3cm 3cm	0 1 2 3				0-none 1-not severe 2-severe	2			
Tongue ventro lateral Right	none <1cm 1-3cm 3cm	0 1 2 3				none not severe severe	0			
Left	none <1cm 1-3cm 3cm	0 1 2 3				none not severe severe	1			
Floor of mouth	none <1cm 1-3cm 3cm	0 1 2 3				none not severe severe	2			
Palate soft	none <1cm 1-3cm 3cm	0 1 2 3				none not severe severe	0			

Hard	none <1cm 1-3cm 3cm	0 1 2 3				none not severe severe	0 1 2			
Score:										

INTERPRETATION:

ULCERATION	PRE TEST SCORE	POST TEST SCORE	**ERYTHEMA**	PRE TEST SCORE	POST TEST SCORE
0-No ulcer 1 – 9 mild , 10 – 18 – moderate, 19 – 27 – severe			0 – No erythema 1 – 9 – not severe 10 – 18 severe erythema		